



Policies And Procedures Of Blood Transfusion Centers Of MOH Hospitals Of Riyadh Region.

General Directorate Of Laboratories And Blood Bank.

Directorate Of Health Affairs Of Riyadh Region.

2018

Index For Policies And Procedures Of Transfusion Service Centers.

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APPLIES TO: Transfusion Service Laboratory staff.

1. Statement Of Purpose:

The purpose of this policy is to provide instructions to all transfusion service laboratory staff of MOH Hospitals at Riyadh Region regarding request of their needs of blood products from central blood bank at Riyadh Regional Laboratory or other MOH hospitals at Riyadh region.

2. Definitions:

2.1. Blood components Request: Is an official request (approved by General Directorate of Riyadh Health Affairs, MOH) for blood products when the facility has a shortage in its blood products inventory.

3. Equipment / Material / Forms :

3.1. Official Request for Blood Components.

3.2. Validated and Temperature monitored thermal cooler.

3.3. Transport vehicle and driver.

4. Policy Statement:

4.1. It is the policy of the Laboratories & Blood Banks Administration, General Directorate of Riyadh Health Affairs, to provide safe and good quality blood products to its hospitals without any delay of transfusion service.

4.2. Assigned technician from requesting hospital shall inform blood banks coordinator assigned at the Laboratories & Blood Banks Administration at General Directorate of Riyadh Health Affairs, to arrange supplying



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their demand of blood products when the facility has a shortage in its blood products inventory.

4.3. Blood banks coordinator assigned at the Laboratories & Blood Banks Administration at General Directorate of Riyadh Health Affairs, should coordinate in supplying the requested blood products according to the available Riyadh region blood products stock and compatible blood groups.

4.4. Assigned technician from requesting hospital should write the official blood products request and arrange validated temperature monitored thermal cooler & driver/transport vehicle.

5.1.1 Policy and procedures of transportation of blood components shall be strictly followed.

5. Procedures

5.1. Requesting the Blood.

5.1.1. Assigned technician from requesting hospital fill the prescribed form according to the advice of director/chief technician, get it stamped by the transfusion service lab director.

5.1.2. Assigned technician from requesting hospital shall send this request to blood banks coordinator assigned at laboratory & blood banks administration at General Directorate of Riyadh Health Affairs, who in turn coordinate supplying the required same blood group



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products or select alternative blood group according to Riyadh region blood products stock as follow:

| PRBCs | | | | |
|-------------|------------------------|------------------|------------------|------------------|
| Patients | 1 st Choice | 1 st | 2 nd | 3 rd |
| Blood Group | Similar Group | Alternate Choice | Alternate Choice | Alternate Choice |
| O | O | No Choice | No Choice | No Choice |
| B | B | O | No Choice | No Choice |
| A | A | O | No Choice | No Choice |
| AB | AB | A | B | O |
| Rh Positive | Rh Positive | Rh Negative | No Choice | No Choice |
| Rh Negative | Rh Negative | *No Choice | No Choice | No Choice |

* If a life threatening condition arises; Patient's physician and transfusion service physician may decide to transfuse Rh Positive blood to Rh Negative patient.

| FFP | | | | |
|-------------|------------------------|------------------|------------------|------------------|
| Patients | 1 st Choice | 1 st | 2 nd | 3 rd |
| Blood Group | Similar Choice | Alternate Choice | Alternate Choice | Alternate Choice |
| O | O | A | B | AB |
| B | B | **AB | No Choice | No Choice |
| A | A | **AB | No Choice | No Choice |
| AB | AB | No Choice | No Choice | No Choice |
| Rh Positive | Rh Positive | Rh Negative | No Choice | No Choice |
| Rh Negative | Rh Negative | *RH POSITIVE | No Choice | No Choice |

* The FFP must be clear without red cells contamination. Avoid transfusing to the females in child bearing age of life. The transfusion service physician permission is essential, so that he can coordinate administration of RhoGm, if indicated.

** Must be no red cell contamination.



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| Platelet Concentrate | | | | |
|----------------------|------------------------|------------------|------------------|------------------|
| Patients | 1 st Choice | 1 st | 2 nd | 3 rd |
| Blood Group | Similar Group | Alternate Choice | Alternate Choice | Alternate Choice |
| O | O | *A | *B | *AB |
| B | B | *AB | *A | O |
| A | A | *AB | *B | O |
| AB | AB | A | B | O |
| Rh Positive | Rh Positive | Rh Negative | No Choice | No Choice |
| Rh Negative | Rh Negative | **RH POSITIVE | No Choice | No Choice |

*The Platelets with less than ½ of red cells contamination can be issued normally. For pedia patients get permission from Patient's physician and blood bank physician before issuing an alternate ABO, Reduce Plasma if ABO incompatible.

**Get permission from blood bank physician, before issuing Rh Positive platelets to Rh Negative patients so that he can coordinate administration of RhoGm, if required.

- 5.1.3. Once supplying facility assigned, requesting hospital's technician arrange for temperature monitored thermal cooler.
- 5.1.4. Assigned technician from requesting hospital hand over the cooler and blood products request to the driver.
- 5.1.5. Driver from requesting hospital head toward assigned supplying facility to receive requested blood products.



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5.2 Receiving of Blood products

5.2.1 Once driver returned, assigned technician from requesting hospital receive the cooler & check the following:

5.2.1.1 All transfer documents available including Transfusion Transmitted Diseases Testing Certificate.

5.2.1.2 Temperature of the cooler is within acceptable limits.

5.2.2 Receive the blood products and inspect it according to visual inspection policy and record blood products received in special Log book if satisfactory, otherwise write an OVAR and hand over to lab director or chief technician.

6. Responsibility:

6.1.It is the responsibility of assigned transfusion service lab to request & receive the blood products from supplying facility.

6.2.It is the responsibility of blood banks coordinator assigned at laboratories & blood banks administration at General Directorate of Riyadh Health Affairs, to review requesting hospital inventory to insure accuracy of the request & also review Riyadh region inventory to arrange supplying same blood group products or select alternative blood groups.



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7. References:

- 7.1. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.
- 7.2. Technical Manual AABB 18th edition, 2014.
- 7.3. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.4. CBAHI national standards for hospitals 3rd edition, 2015.



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7. Approvals:

| | Name | Title | Signature | Date |
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| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab | | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab | | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair | | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab | | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. | | 1-5-2018 |



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| <u>TITLE:</u> Blood Components Inventory Control. | | | |
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1. Statement Of Purpose:

The purpose of this policy is to provide guidance in ensuring optimum availability of minimum inventory of blood products by determining minimum required inventory level of blood products.

2. Definitions:

2.1. The Minimum inventory level: Estimated minimum level of blood products taking into consideration the availability of adequate supplies of blood for routine and emergency situations.

3. Equipment / Material /Forms :

3.1. Issue register.

3.2. Inventory register.

4. Policy Statement:

4.1. It is the policy of blood bank to appropriately determine the minimum inventory level of blood and blood product to assure adequate supply of blood products to its clients & arrange to request the required units from central blood bank.

5. Procedure:

5.1. Average Daily Use Estimate

Facilities that transfuse on a daily basis may calculate daily blood usage by the following method.

5.1.1. Determine the total use over 6 months for each blood product and Blood Group.



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5.1.2. Divide the total use by the number of days in the period covered.

5.2. Calculating Minimum Inventory Level:

5.2.1. Determine the minimum inventory level by multiplying the daily use by the 7 days of blood supply.

5.3 Daily RBCs Inventory :

Every morning, the night shift technologist should ascertain the RBCs inventory using the following procedure:

5.3.1 Cancel and return any units that were cross-matched 24 hours ago to the available stock unless there is a notification to hold the blood until the 2nd calendar day.

5.3.2 Cancel and return to the available stock any units that were reserved for a neonate top-up transfusion if the patient is discharged.

5.3.3 Place the cancelled units back into the stock refrigerator according to Group/Rh and expiration date (the older units are placed at the front left-hand corner of each shelf).

5.3.3.1 Remove any expired units from the blood stock refrigerators.

5.3.3.2 Place the expired units in the untested blood refrigerator located in the component room to be used for QC or Discard.



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5.3.4 Transfer the neonatal units that are more than 14 days old to the other shelves according to Group/Rh and expiration date (the older units are placed at the front left-hand corner of each shelf).

5.3.5 Discard the expired units.

5.3.6 Count the numbers of units in the stock refrigerators then record it as follow:

5.3.6.1 Number of cross-matched units.

5.3.6.2 Numbers of blood unit in ER.

5.3.6.3 Numbers of test results pending units in the component room refrigerator.

5.3.6.4 Number of short expiry RBC units (including cross-matched units).

5.4 Weekly Frozen Inventory Every Saturday, the component room staff should ascertain the frozen components inventory using the following procedure:

5.4.1 Check the freezers to be sure that the oldest FFPs and CRYOs are placed at the front left-hand corner of each shelf.

5.4.2 Count the total number FFPs and CRYO units then record.

5.4.3 Complete the weekly frozen inventory report.



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5.1.1 Policy & procedures of requesting blood products from other MOH health facility shall be strictly followed.

6 Responsibility:

6.1 It is responsibility of technician assigned in inventory section to carry out the calculation and maintain this minimum level of stock.

6.2 It is responsibility of Lab director/medical director in case of inability to meet the requirement to arrange with central blood bank to insure supply of weekly required inventory level of blood products.

7 References:

7.1. Technical Manual AABB 18th edition, 2014.






7.2. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.3. CBAHI national standards for hospitals 3rd edition, 2015.



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8. Approvals:

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| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE:</u> Storage And Retention Of Blood Samples. | | | |
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1. Statement of Purpose :

The purpose of this policy is to provide instructions to transfusion service laboratory staff about accurate required storage and retention of both; patients' blood samples & Segment/specimens from transfused RBC units.

2. Definitions:

2.1. Blood Sample/Specimen: A little amount of blood collected from a patient or donors' transfusion units in an appropriate tube for clinical testing.

3. Equipment/Material/Forms

3.1 Blood samples.

3.2 Refrigerator reserved for blood samples.

4. Policy Statement:

4.1 The sample retention policy ensures that donors units and patients samples are stored and retained under appropriate conditions for no less than the periods specified below:

- a- Outpatient specimens (not for compatibility testing) are retained for twenty-four hours.
- b- Inpatient specimens are retained for seventy-two hours.
- c- Specimens of patients who receive blood transfusion are retained for seven days after transfusion.



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- d- Segment/specimens from transfused RBC are retained for seven days after transfusion.
- e- Specimens for transfusion reaction investigation are retained for seven days.

5. Procedure:

5.1 Outpatient specimens (not for compatibility testing) are retained for 24 hours in the designated fridge and drawer then remove 24 old samples of the same day from the drawer and discard in yellow sharp waste container

5.2. Inpatient Samples specimens are retained for 72 hours in the designated fridge and drawer then remove 72 old samples of the same day from the drawer and discard in yellow sharp waste container.

5.3 Patient Samples specimens who will receive blood transfusion with Segment/specimens from their transfused RBC & also specimens for transfusion reaction investigation should be stored and retained as follow:

- 5.3.1 Keep all typed and screened or cross Matched samples (compatibility testing) arranged in sequence in the rack of the same day on the reception bench as soon as the testing is complete.
- 5.3.2 Keep all typed and screened or cross matched samples (compatibility testing) arranged in sequence for 72 hours in the designated fridge and drawer. Remove and shift 72 old sample to the blood sample storage fridge to complete one week.



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5.3.3 Remove one week old samples of the same day from the drawer and discard in yellow sharp waste container.

5.3.4 Monitoring & maintenance of blood sample storage fridge SOP shall be strictly followed.

6. Responsibility:

6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service Laboratory to perform the procedure accurately.

6.2 It is the responsibility of assigned physician to assure implementation of policies and procedure.

7. References:

7.1 AABB Standards 30th edition 2016.

7.2 Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.

7.3 Technical Manual AABB 18th edition, 2014.

7.4 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

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| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. | | 1-5-2018 |



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| <u>TITLE</u> Storage Of Blood Components. | | | |
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1. Statement of Purpose :

The purpose of this policy is provide guidance to transfusion service laboratory staff about storage of blood and its components and also strictly observing blood storage within temperature limits.

2. Definitions :

1.1 Inventory: level of blood and blood products that ensure availability of adequate supplies of blood components units for routine and emergency situations.

3. Equipment/Material/Forms:

3.1 Blood bank refrigerator (1-6 °C).

3.2 Blood bank freezer. (-20 °C).

3.3 Thermometers.

3.4 Blood bank inventory registration log book.

3.5 Blood release (Traceability) documents.

3.6 Temperature monitoring forms.

4. Policy Statement: It is the policy of transfusion service lab to:

4.1 To confirm that storage devices shall have the capacity and design to ensure that the proper temperature is maintained.

4.2 To specify the shelf life of each blood component.

4.3 To confirm monitoring of internal storage temperatures of refrigerators, freezers.

4.4 To confirm that storage devices for blood and blood components have alarms .The alarm shall be set to activate under conditions that will allow proper



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action to be taken before blood, blood components reach unacceptable conditions.

4.5 Activation of the alarm shall initiate a process for immediate investigation and appropriate corrective action.

4.6 To confirm that warming devices for blood and blood components shall be equipped with a temperature-sensing device and a warning system to detect malfunctions and prevent hemolysis or other damage to blood or blood components.

5. Procedure :

5.1 For storage of blood or blood components, the temperature shall be continuously monitored or the temperature shall be recorded at least every 4 hours.

5.2 If blood or blood components are stored in an open storage area, the ambient temperature shall be recorded at least every 4 hours.

5.3 Access to storage areas and authorization to remove contents shall be controlled.

5.4 Blood and blood components must be stored in a manner that prevent damage , limlits deterioration and meets the following requirements :

5.4.1 Paked red blood cells (PRBCs) must be stored at 1 – 6 °C .

5.4.2 Fresh frozen plasma (FFP) must be stored at $\leq -18^{\circ}\text{C}$.

5.4.3 Cryoprecipitate (CRYO) must be stored at $\leq -18^{\circ}\text{C}$.

5.4.4 Platlet concentrates (PC) are not stored as per our scope of servive (blood transfusion center), Platlet concentrates are ordered on request



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form treating physcain,then the request will be sent to central blood bank, and transfused immediately to the pateint , policy & procedure of of request and receive the blood products From central blood bank are applied .

5.4.5 Policy & procedure of tansportaion of blood components shall be strictly followed.

5.4.6 Policy & procedure of monitoring & maintenance of the blood products storage equipment's shall be strictly followed.

Storage and Expiration of blood and its components table .

| Component | Storage | Expiration |
|----------------------------------|---------|--|
| Red Blood Cell Components | | |
| Packed Red Blood Cells (PRBCs) | 1-6 C | ACD/CPD/CP2D: 21 days CPDA-1: 35 days <u>Additive solution 42days *</u> Open system: 24hours |
| PRBCs Irradiated | 1-6 C | Original expiration or 28 days from date of irradiation, whichever is sooner |
| Plasma Components | | |
| Fresh Frozen Plasma (FFP) | <-18 C | <u><-18 C: 12 months from original collection.</u> |
| FFP (after thawing) | 1-6 C | <u>I 24 Hours after thawing.</u> |
| Cryoprecipitate | <-18 C | 12 Months from original collection. |
| Cryoprecipitate (after thawing) | 1-6 C | 6 hours from the thawing time for individual units and 4 hours from the thawing time of pooled units. |

* Current blood bags used in MOH hospital are with additive solution.



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6. Responsibility:

- 6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service Laboratory to perform the procedure accurately.
- 6.2 It is the responsibility of assigned physician to assure implementation of policies and procedure.






7. References:

- 7.1 AABB Standards 30th edition 2016.
- 7.2 Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.
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| APPLIES TO: Transfusion Service Laboratory staff. | | | |

8. Approvals:

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| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
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| <u>TITLE:</u> Monitoring & Maintenance Of The Blood Products Storage Equipment's. | | | |
| <u>EFFECTIVE DATE</u> 04- 06- 2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-5 -V1 | <u>NUMBER OF PAGES:</u> 5 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide instruction to transfusion service laboratory staff to monitor & maintain the blood products storage equipment's (deep freezers, refrigerators) cleanliness and record temperature.

2. Definition:

2.1. **Calibration** is Comparison of measurements performed by an instrument to those made by a more accurate instrument or standard for the purpose of detecting, reporting, and eliminating errors in measurement.

3. Equipment / Material /Forms :

- 3.1. Refrigerators.
- 3.2. Deep Freezers.
- 3.3. Wet Cloth/Cotton Gauze.
- 3.4. Gloves.
- 3.5. Disinfectant.
- 3.6. Thermometers.
- 3.7. Standard Thermometer.

4. **Policy Statement:** it is the policy that transfusion services use appropriate blood and blood components storage devices with proper monitoring & maintenance of the blood products storage equipment's as follow:

4.1 The blood and blood components storage devices are:

- a- Designed for the intended use.



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APPLIES TO: Transfusion Service Laboratory staff.

- b- Equipped with continuous temperature monitoring system (temperature recording).
- c- Equipped with audio/visual alarm systems.

4.2 The device's alarm and monitoring system conforms with the following:

- a- Activates at a temperature that allows for intervention before the contents reaches unacceptable temperature.
- b- Activates at an area staffed 24 hours a day, seven days a week.
- c- Connected to a separate DC power supply.
- d- The alarm system is checked weekly.
- e- Alarm activation temperatures are checked quarterly.
- f- The inner temperature of blood storage devices is monitored and recorded at least once a day using a standardized thermometric device.
- g- In the event of failure of continuous temperature monitoring, temperature recording, or alarm systems, the inner temperature is monitored and recorded every four hours.

4.3 Monitor temperature of all blood storage equipment. The alarms shall be set as follow:

| | | Refrigerators | Deep Freezer |
|------------|------|---------------|----------------|
| Pre- Alarm | High | 5.5 °C | -20.0 °C |
| | Low | 1.5 °C | Not applicable |
| Alarm | High | 6.0 °C | -18.0 °C |
| | Low | 1.0 °C | Not applicable |



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4.4 Temperature should be recorded every 4 hours.

4.5 Keep temperature sensors inside the fridges in a volume of 10% Glycerol equal to the blood unit.

4.6 Weekly Check alarms are functioning for all devices.

4.7 Clean the exterior of the blood storage equipment by wet cloth daily and disinfect its exterior and interior monthly.

4.8 Clean the filter of all blood products storage equipment's monthly.

5 Procedure:

5.1 Daily Temperature Recording:

5.1.1 Observe the equipment door closing, Check all two/three thermometers' reading and see if they are in ± 1 °C difference than each other. If the difference is more than 1, call the maintenance for calibration.

5.1.2 Weakly Check if alarm is working and record alarm and temperature in the chart.

5.2 Alarm Activation

5.2.1 Bring one cup of water and arrange its temperature by adding ice in it to 6 °C and 1°C to alarm limits turn by turn

5.2.2 Remove the probe from the glycerol water bottle in the equipment and put in cup of water at 6 °C and 1°C. Alarm shall ring, if not so test again if, still not ring call maintenance for repair.



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5.2.3 If the temperature probe is built in any equipment, keep the door open till it reaches the alarm limit and alarm rings; if not so call maintenance for repair.

5.3 Filter Cleaning:

5.3.1 Send request to maintenance department for filter cleaning of these equipment every month.

6 Responsibility:

6.1 It is the responsibility of inventory technician to record daily temperature and activate the alarms.

6.2 It is the responsibility of quality control officer to print daily temperature reports for central monitoring system and observe any deviation.

6.3 Laboratory director is responsible to decide the fate of products; if a deviation in temperature is observed.

7 References:

7.1. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.2. Technical Manual AABB 18th edition, 2014.

7.3. CBAHI national standards for hospitals 3rd edition, 2015.



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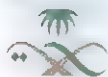
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APPLIES TO: Transfusion Service Laboratory staff.

8. Approvals:

| | Name | Title | Signature | Date |
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| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
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| <u>TITLE:</u> Transportation of Blood Components. | | | |
| <u>EFFECTIVE DATE</u> 04- 06- 2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-6 -V1 | <u>NUMBER OF PAGES:</u> 5 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. **Statement of Purpose :**

The purpose of this policy is provide guidance to transfusion service laboratory staff to transport blood components accurately and strictly observing blood transport measures and blood transport temperature limits .

2. **Definitions :**

2.1 Corrugated Cardboard is a paper-based consisting of a fluted corrugated sheet and one or two liner boards. It is widely used in the manufacture of corrugated boxes and shipping containers.

3. **Equipment / Material /Forms :**

3.1 Blood transport thermal container with thermometer.

3.2 Ice/water packs kept at (-20 °C) overnight

3.3 Corrugated cardboard.

3.4 Transport labels / receiving facility address.

3.5 Blood release (Traceability) documents.

4. **Policy Statement :**

4.1 It is the policy of transfusion service lab to transport blood products in a validated cooler.

4.2 It is the policy of transfusion service lab that each blood or blood component type shall be package in separate containers. The products that requiring similar range of temperature may be transported in a single container.

4.3 FFP & Cryoprecipitate may be transported frozen, and in this condition should be stayed frozen in properly insulated container during shipment



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4.4-PRBCs, and plasma products (after thawing) must be transported in properly insulated container at a temperature of **1° to 10° C**. In order to avoid hemolysis, the Whole Blood, PRBCs, and segments should never come into direct contact with the bagged ice or cooling pack.

4.5 Platelets components are transported in properly insulated container as close as possible to **20 and 24°C**.

4.6 Thawed Cryoprecipitate should be kept at ambient room temperature

4.7 It is the policy of transfusion service lab that blood, blood component for transport should remain in temperature monitored storage device (refrigerator /freezer) until such time as the transport container has been prepared to appropriate ambient temperature packing scheme. The blood, blood components should be removed from the storage device directly into the properly transport container closed, security sealed and transported immediately.

4.8 This policy does not include the transport of blood, blood components accompanying a patient intended for transfusion during transport or at arrival at another facility.



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5. Procedure :

5.1 Transports inside the Facility:

- 5.1.1 Assure the transport container by visually inspecting for integrity of the outer surface, the lid and the inner surface. Also, ensure the inner surface is clean and dry.
- 5.1.2 Prepare the cooler according to the product type and keep the blood products in cooler.
- 5.1.3 Keep the documents /compatibility testing reports in leak proof zipper envelop.
- 5.1.4 Close the coolers lid property.
- 5.1.5 Hand over the container to the transporter.
- 5.1.6 Assure the cooler has label (Blood Product).

5.2 Transport in the Riyadh region by vehicle accompanying a transporter.

- 5.2.1 Assure the transport container by visually inspecting for in integrity of the outer surface, the lid and the inner surface. Also, ensure the inner is clean and dry.

5.3 PRBC:

- a. Keep the PRBC units inside the container.
- b. Keep a corrugated card board above the units.
- c. Keeps 2-4 ice packs in zipper bag above the card board
- d. Keep the documents in zipper bag in the cooler
- e. Close the lid and hand over to porter.



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5.3 FFP & cryoprecipitate:

- a. Keep 2-4 ice packs in the cooler.
- b. Keep plasma bags over the ice packs.
- c. Keep 2-4 ice packs above the FFP or cryo bags.
- d. Keep a card board sheet above ice pack.
- e. Keep documents over card board in a zipper bag.

5.4 Platelet Concentrate :

- a. Keep platelet bags in the cooler.
- b. Keep documents in a zipper bag.

6. Responsibility :

6.1 It is the responsibility of transfusion service lab staff assigned to comply of this policy and procedure, compliance to this will be monitored by the lab physician.

7. Reference :

- 7.1** Guide lines for the blood transfusion services UK 2008.
- 7.2** Technical Manual American of Blood Banks, 18th edition 2014.
- 7.3** Standards for Blood Bank and Transfusion Services .Bethesda, MD:
American Association of Blood Bank 30th edition, 2016.



TITLE: Transportation of Blood Components.

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APPLIES TO: Transfusion Service Laboratory staff.

8. Approvals:

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| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab | | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. | | 1-5-2018 |



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|--|--|--|-------------------------------------|
| <u>TITLE</u> Accepting Transfusion Requests And Determining Specimen Suitability. | | | |
| <u>EFFECTIVE DATE</u> 04- 06- 2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-7 -V1 | <u>NUMBER OF PAGES:</u> 8 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement of Purpose :

The purpose of this policy to provide guidance to transfusion service laboratory staff about accepting transfusion requests and determining specimen suitability in a correct way.

2. Definitions :

2.1 Document: to capture information for use in documents through writing or electronic media.

2.2 Label: an inscription fixed to a blood component or blood product for identification.

2.3 Licensed Physician: a physician licensed to practice medicine.

3. Equipment / Material /Forms :

3.1 Transfusion requests or electronic order entry.

3.2 Specimen(s).

4. . Policy Statement:

4.1 It is the policy of transfusion service lab staff to provide guidance and pathway to medical staff to go through all process smoothly without errors as majority of ABO- incompatible transfusion are due to documentation/Identification errors.

4.2 Requests for blood, blood components, tests and records accompanying blood samples from the patient shall contain sufficient information to uniquely identify the patient, including **two independent identifiers**.



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4.3 The transfusion service shall accept only complete, accurate, and legible requests, in case of discrepancy or doubt, the officer-in-charge of the blood bank shall be noted.

4.4 Unlabeled samples **shall** be discarded.

5. Procedure:

5.1 Blood Specimen:

5.1.1 Check the specimen to ensure that the following requirements have been met:

5.1.1.1.1 a full 7ml lavender top vacutainer tube (EDTA) is required. A minimum of 3ml from adults, 2ml from pediatric and 1ml from neonates can be accepted.

5.1.1.1.2 Tube is firmly stoppered.

5.1.1.1.3 Label is firmly attached.

5.1.1.1.4 Label information matches with information on the order.

5.1.1.1.5 Label information includes:

- Patient's full name (at least three names) is a must.
- Patient number is a must.
- Date and time of specimen drawn.
- ID number/Initial of phlebotomist.



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5.1.2 Do not receive the sample if:

- a. Sample is older than 48 hours (Validity of sample for compatibility is 72 hours).
- b. The tube is crack or broken.
- c. The label is inadequately attached.
- d. The label information is incomplete.
- e. Inadequate volume for testing.
- f. The specimen date is different than date of collection.
- j. The information on label does not match with request.
- k. Specimen is hemolyzed (except in rare cases can accept partially hemolysed sample).
- l. Overwriting on the sample.

5.1.3 Look and try to judge, if the specimen is taken from IV Line.

- a. Sample looks very low Hb/HCT as compared with the Hb mentioned on the request.
- b. Sample is clotted.
- c. Sample is not collected in EDTA tube (Exceptionally for special circumstances plain tube specimen can be accepted also).

5.1.4 If the sample is rejected for one of the above reason:

- a. Record the information in sample rejection form.



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- b. Return only the request to porter with remarks on the request stating the defect.
- c. Don't return the rejected sample to the ward.
- d. If the sample is already received and discrepancy is detected later, call the concern section and notify them that sample must be recollected.
- e. Cancel the order if no new sample came.

5.1.5 If the sample does not meet the criteria and patient's condition requires accepting the sample, take the approval from Medical Director/Blood Bank Physician to accept the sample.

5.2 Transfusion Request form:

5.2.1 The request is on prescribed form.

5.2.2 Patient information is complete and matches with the sample (Three names and File Number).

5.2.3 It is signed and stamped by a physician.

5.2.4 Two staff members verify the patient's identity prior to blood drawing for cross match.

5.2.5 Patient's diagnosis is written.

5.2.6 For PRBC Patient Hb/HCT, For FFP and cryoprecipitate INR and for platelet concentrate platelet count is mentioned.

5.2.7 Receptionist must write the time of receiving the request and sign.



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5.3 Blood Test Request:

5.3.1 The request is on prescribed form.

5.3.2 Patient information is complete and matches with the sample.

5.3.3 It is signed by a physician.

5.3.4 Patient diagnosis is written.

5.4 If the request & sample are accepted, Hand over them to assigned technician.

6. Responsibility:

6.1 It is the responsibility of assigned technologist/technician work in transfusion service laboratory to follow procedure instruction.

6.2 It is the responsibility of assigned physician assigned in the area to insure implementation of the policy and procedures.

7. References:

7.1 Technical Manual American of Blood Banks, 18th edition 2014.

7.2 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.3 CBAHI national standards for hospitals 3rd edition, 2015.

7.4 Guide lines for the blood transfusion services UK 2008.

7.5 Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.



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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

- 7.6 Canadian Standards for Transfusion Medicine. CSTM standards for hospital transfusion services Version 3.0. Ottawa: Canadian Society for Transfusion Medicine; 2011.
- 7.7 Manitoba Provincial Blood Coordinating Office. Manitoba transfusion quality manual for blood banks Version 2.0. Winnipeg (MB). Manitoba Provincial Blood Programs Coordinating Office; 2007.
- 7.8 Roback, J., Grossman, B., Harris, T & Hillier, C. Technical manual, Bethesda, Maryland: AABB; 18th edition 2014.
- 7.9 Sharpe, Gail. Determining specimen acceptability PRC-TRM-002 Version 1.0. St. John's NL: Eastern Health; 2010.



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EFFECTIVE DATE
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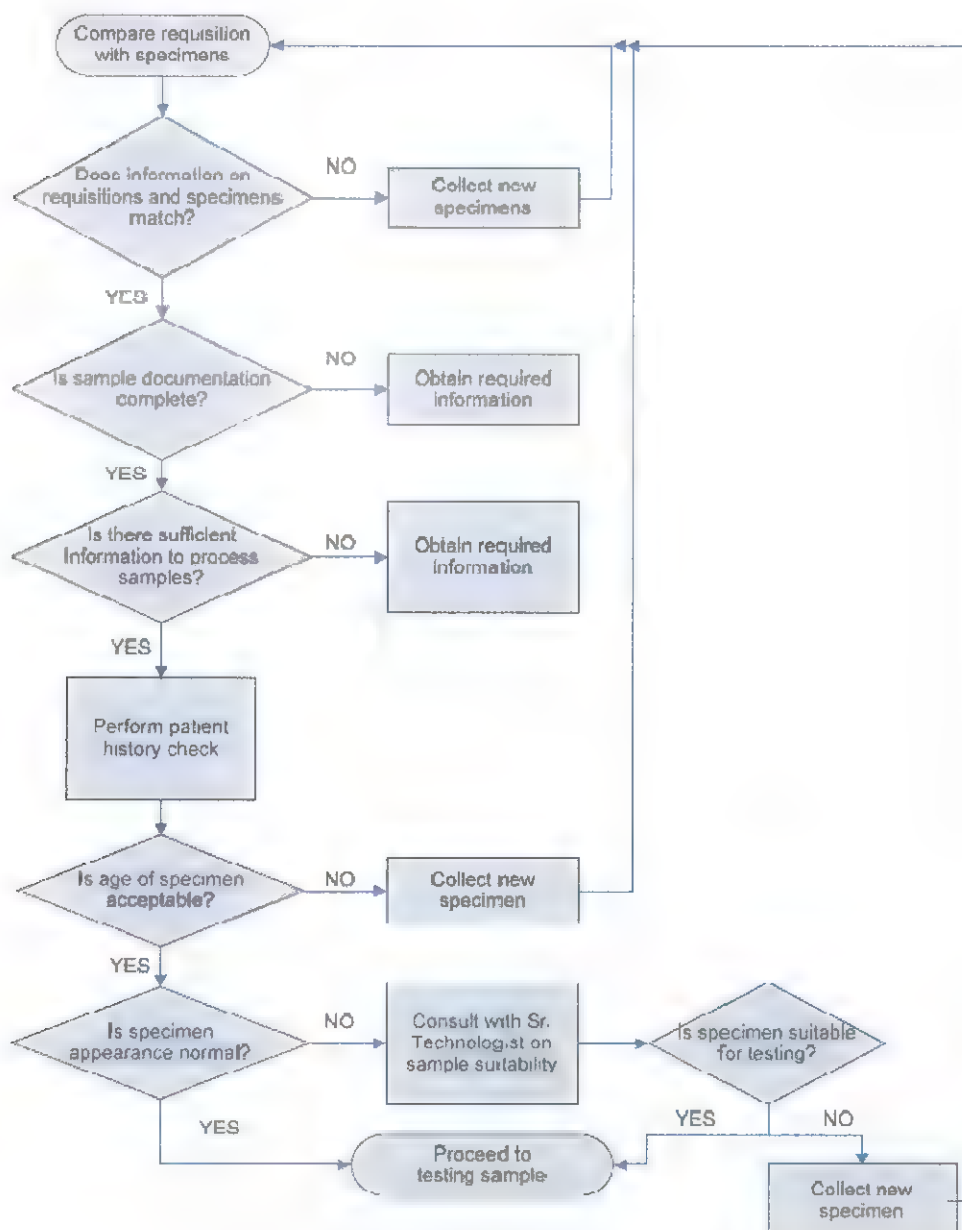
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Flow chart of comparing the requisition of transfusion and specimen label before testing.





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| APPLIES TO: Transfusion Service Laboratory staff. | | | |

8. Approvals:

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TITLE: Pre Transfusion Tests Sequence.

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APPLIES TO: Transfusion Service Laboratory staff.

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff about pre transfusion tests sequence.

2. Definitions:

2.1 Pretransfusion Testing: group of laboratory tests performed before blood transfusion to ensure transfusion of specific compatible red blood cell components to recipients and include ABO group, Rh type, unexpected antibodies to red cell antigens and cross-matching.

2.2 Blood Order/Request: is a physician's prescription to transfuse a blood product to a patient.

3. Equipment/Material/Forms:

3.1 Transfusion request and sample.

3.2 EDTA Blood specimen from patient.

4. Policy Statement:

4.1. It is the policy to ensure that recipient should receive specific compatible red blood cell components by correct pre transfusion tests sequence.

4.2. The transfusion services implement a system for pretransfusion testing of the recipient as follow:

4.2.1. Pre-transfusion testing is performed on a specimen collected from the recipient with every admission and within three days of the scheduled transfusion time.



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4.2.2. There is a consistency between patient's current and historical records (including ABO/Rh group and antibody screening). Discrepancies are resolved before performing compatibility testing, Otherwise issue O PRBCs or AB FFP/ AB Platelets in emergency.

4.2.3. When there is no history for the patient in the transfusion services records or computer system, two determinations of the patients ABO/RhD must be made on two specimens collected during the current admission.

4.2.4. Pre-transfusion testing includes:

- Determination of the patient's forward ABO group (RBC grouping).
- Determination of the patient's reverse ABO group (Serum Grouping) except for infants less than 4 months age.
- Determination of the patient's Rh-D type.
- Detection and Identification (if applicable) of unexpected antibodies to red cell antigens.

4.2.5. Patient' samples and a segment from any red-cell-containing component(s) shall be stored at refrigerated temperatures for at least 7 days after transfusion.

5. Procedure

5.1 Perform the blood group and Rh factor for donor's untis and recipients according to blood grouping policy.

5.2 Perform anti body screen for recipients according to antibody screening policy.



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5.3 Check patient transfusion/antibody screen/Blood grouping history (if available).

5.4 If Anti body screen reveals negative antibodies and no clinical significant history exists then select similar blood group or alternate according to following tables. **Perform immediate spin** for all routine RBCS transfusions.

5.5 **Stop at type and screen phase** if the request is requiring type and screen for minor surgeries or the request is **stand by** and no one call from the ward.

5.6 If antibody screen reveals negative but patient has a history of clinical significant antibody, select corresponding antigen negative PRBC units and proceed to complete cross - match.

5.7 If **Antibody screen reveals positive** proceed to antibody identification.

5.8 If similar ABO and Rh group PRBCs are not available, select ABO and Rh alternate units according to following:



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Selection of alternate Blood group unit table:

| Patient's Blood Group | 1 st Choice | 2 nd Choice | 3 rd Choice | 4 th Choice |
|-----------------------|------------------------|------------------------|------------------------|------------------------|
| O | O | No Choice | No Choice | No Choice |
| B | B | O | No Choice | No Choice |
| A | A | O | No Choice | No Choice |
| AB | AB | A | B | O |
| Rh Positive | Rh Positive | Rh Negative | No Choice | No Choice |
| Rh Negative | Rh Negative | *under restriction | No Choice | No Choice |
| O red Cells | O red Cells | No Choice | No Choice | No Choice |
| AB FFP/Plts | AB FFP/Plts | No Choice | No Choice | No Choice |
| Rh Negative products | Rh Negative products | No Choice | No Choice | No Choice |

*; Patient's physician and blood bank physician may decide to transfuse Rh Positive blood to Rh Negative patient in the following conditions :

- If the patient is male or female after the age of menopause and in a life threatening condition or the blood bank' stock of Rh negative is less than 10 units and also the patient shouldn't have anti-D.

5.9 Check all the units visually before starting the cross-match. Note following defects carefully.

- Hemolysis, clots and proper labeling.
- Units' expiry date for validity.
- Finalize the request and issue the unit according to the type of request.
- Store sample for all above patients in a designated rack.

5.10 Perform immediate spin cross-match according to policy by taking the request from file, and specimen from specimen fridge or from the bench accordingly, if physician call for blood for typed and screened requests or standby requests.



TITLE: Pre Transfusion Tests Sequence.

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APPLIES TO: Transfusion Service Laboratory staff.

6. Responsibility:

6.1 It is the responsibility of transfusion service laboratory technician/technologist to perform the job.

6.2 The physician assigned in the transfusion service laboratory is responsible for observation of proper processing of blood products request.

7. References:

7.1 Technical Manual American of Blood Banks, 18th edition 2014.

7.2 Guide lines for the blood transfusion services UK 2008.

7.3 Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.




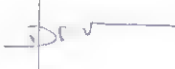

7.4 Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.

7.5 National hospital standards(3rd edition) Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI); 2015.



| | | | |
|--|-------------------------------------|------------------------------------|------------------------------|
| TITLE: Pre Transfusion Tests Sequence. | | | |
| EFFECTIVE DATE: 04-06-2018 | REVISION DATE: 03-06-2020 | INDEX NO: APP-LB-BB-8-V1 | NUMBER OF PAGES: 6 |
| APPLIES TO: Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|--------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



| | | | |
|---|--|---|-------------------------------------|
| <u>TITLE:</u> Grading Of Serological Reaction. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-9-V1 | <u>NUMBER OF PAGES:</u> 5 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform grading of serological reaction without errors.

2. Definitions:

2.1 Agglutination is the clumping of antigen bearing red blood cells with the specific antibodies.

2.2 Agglutination/Reaction grade is visual estimated measure of a serological reaction's strength or intensity.

3. Equipment/Material/Forms:

3.1 Tube or gel card to read.

3.2 Comparison Chart.

4. Policy Statement:

4.1. It is the policy of transfusion service lab to read serological reaction in uniform grades.

5. Procedure

5.1. Tube Method

5.1.1. Continue gentle mixing till all cells are suspended-by tilting the tube or gentle mixing. Cell button must not strike the tube wall. Mix by fluid movement.

5.1.2. Observe that the cells are dispersed from the button.

5.1.3. Tilt tube, read and grade reaction.

5.1.4. Swirling = negative.



| | | | |
|---|--|---|-------------------------------------|
| <u>TITLE:</u> Grading Of Serological Reaction. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-8-V1 | <u>NUMBER OF PAGES:</u> 5 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

5.1.5. Coming in chunks = positive.

5.1.6. Interpretation

| Description | Grade |
|--|------------------|
| ✓ Hemolysis | H |
| ✓ Button remain in one large clump or breaks into two to three large clumps. ✓ Clear background | 4+ |
| ✓ Button breaks into many large clumps after being dislodged. ✓ Clear background | 3+ |
| ✓ Button breaks into many small clumps after being dislodged. ✓ Slightly cloudy background | 2+ |
| ✓ Button breaks into numerous tiny clumps after being dislodged. ✓ Cloudy background | 1+ |
| ✓ Button breaks into many fine agglutinins after being dislodged. ✓ Free-cells background | W+ |
| ✓ Button breaks into medium to large clumps after being dislodged. ✓ Free-cells background | MF (Mixed field) |



TITLE: Grading Of Serological Reaction.

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APPLIES TO: Transfusion Service Laboratory staff.

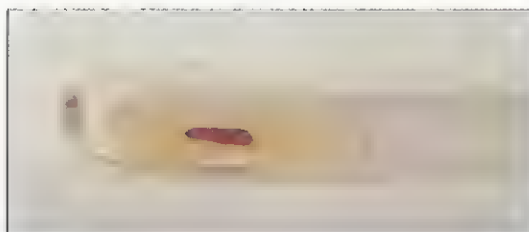
5.1.7. Procedure Notes

5.1.7.1 Over shaking may break up large agglutinates.

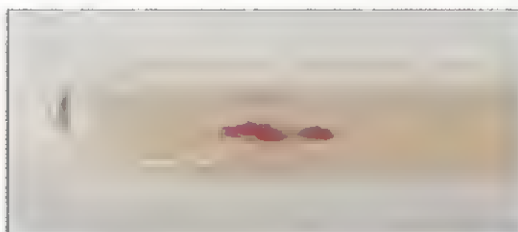
5.1.7.2 The strength of the agglutination or degree of hemolysis observed with each tube must be recorded (on the patient file card or in the computer) as it is read.

5.1.7.3 The character of the agglutination should be noted and recorded. Loose or mixed-field agglutinates should be noted as they provide valuable clues in the investigation of unexpected finding.

5.1.7.4 Grading For tube Seriological Reactions:



4+ Reaction



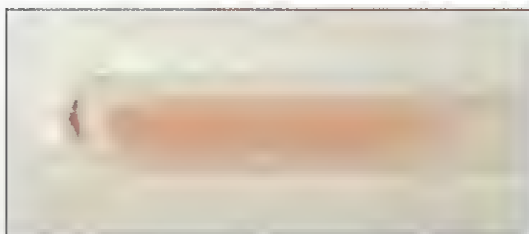
3+ Reaction



2+ Reaction



1+ Reaction



Hemolysis



Negative reaction



TITLE: Grading Of Serological Reaction.

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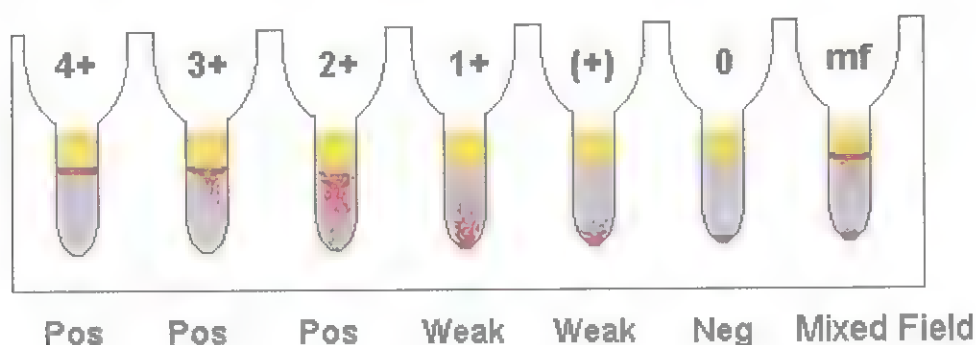
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APPLIES TO: Transfusion Service Laboratory staff.

5.2. Gel Cards

5.2.1. Compare reaction in gel cards with the charts:-



6. Responsibility:

- 6.1. It is the responsibility of assigned technologist/technician reading the reaction to grade it accurately.
- 6.2. It is the responsibility of assigned physician assigned in the area to assure uniform grading among all staff.






7. References:

- 7.1. Technical Manual AABB 18th edition, 2014.
- 7.2. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.3. CBAHI national standards for hospitals 3rd edition, 2015.
- 7.4. Leaflet from DiaMed for ID Liss Coombs Cards and ID DiaCell Panel.
- 7.5. Pictures provided by DiaMed for grading the reactions.



| | | | |
|---|--------------|------------------------------------|------------------------------|
| Grading Of Serological Reaction. | | | |
| 04- 06- 2018 | 03- 06- 2020 | INDEX NO: APP-LB-BB-9-V1 | NUMBER OF PAGES: 5 |
| Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|--------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15-4-2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 14-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



TITLE: ABO Grouping tube method (Forward Grouping).

EFFECTIVE DATE
04- 06 -2018

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APPLIES TO: Transfusion Service Laboratory staff.

1. Statement of Purpose

The purpose of this policy is to provide guidance to transfusion service laboratory staff in cross-matching laboratory to determine the ABO group (forward grouping) by tube method smoothly and in a correct way.

2. Definitions:

2.1 Accuracy of a measurement system is the degree of closeness of measurements of a quantity to that quantity's actual (true) value.

2.2 Agglutination is clumping of red blood cells in the presence of an antibody.

3. Equipment /Material /Forms :

3.1 For all transfusion service testing, a full 7ml lavender top vacutainer tube (EDTA) is required. A minimum of 3ml from adults, 2ml from pediatric and 1ml from neonates can be accepted.

3.2 Patients Transfusion Request / laboratory registration log book.

3.3 Materials:

3.3.1 0.9% normal saline.

3.3.2 Anti-A.

3.3.3 Anti-B.

3.3.4 Anti-A, B (optional).

3.3.5 12x75mm test tubes.

3.3.6 Plastic pipettes.



| | | | |
|---|--|---|-------------------------------------|
| <u>TITLE:</u> ABO Grouping tube method (Forward Grouping). | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-10 -V1 | <u>NUMBER OF PAGES:</u> 8 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

3.3.7 Centrifuge.

3.3.8 Agglutination viewer.

4. **Policy Statement:**

- 4.1 It is the policy of transfusion service lab to perform forward ABO group for all blood units, all recipients including infants less than 4 months of age.
- 4.2 It is the policy of transfusion service lab to determine forward ABO blood groups by testing the red cells for the presence or absence of A and B antigens.
- 4.3 It is the policy of transfusion service lab to perform tube method for ABO blood grouping by observing for agglutination or hemolysis. Absence of agglutination is a negative test result while Presence of agglutination or hemolysis of red cells is a positive test result (see table below). Testing is performed at room temperature.

5 **Procedure**

- 5.1.1 Place 1 drop of Anti-A, Anti-B and Anti-A, B (optional), respectively, in properly labeled 12x75mm test tubes .
- 5.1.2 Add 1 drop of an approximate 3-4% suspension of the red blood cells to be tested to each tube.
- 5.1.3 Mix thoroughly by shaking the tube and centrifuge for a time appropriate to the calibration of the centrifuge (refer to the latest centrifuge settings).
- 5.1.4 Examine for the absence of hemolysis and then re-suspend the cells by gentle shaking.



TITLE: ABO Grouping tube method (Forward Grouping).

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APPLIES TO: Transfusion Service Laboratory staff.

5.1.5 Read macroscopically for agglutination and record test results. For grading of the agglutination results, refer to Grading of sereological reaction.

5.1.6 Interpretation of the results as follow:

| | Anti A | Anti B | Anti D |
|-----------|--------|--------|--------|
| O | 0 | 0 | 0 |
| A | + | 0 | + |
| B | 0 | + | + |
| AB | + | + | + |

5.1.7 When a discrepancy is observed between the current sample blood group result and the historical results, call the ward and ask for a new sample, proceed with the following:

If the new sample confirms the historical blood group:

- 1. Accept the result.*
- 2. Generate OVAR and attach a copy of the laboratory request form.*
- 3. Refer the issue to the lab director.*

If the new sample confirms the current blood group:

- 4. Change the historical blood group.*
- 5. Write your comment as follow :(on DD/MM/YYYY, patient ABO/Rh was on DD/MM/YYYY, the patient's ABO/Rh found to be).*
- 6. Generate OVAR and attach a copy of the laboratory request form.*
- 7. Refer the issue to the lab director.*



TITLE: ABO Grouping tube method (Forward Grouping).

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APPLIES TO: Transfusion Service Laboratory staff.

5.1.8 Limitations for tube method: Factors that may cause false test results include the following:

5.1.8.1 Contamination of blood specimens, reagent and/or supplementary materials.

5.1.8.2 Aged blood specimens may yield weaker reactions than those obtained with fresh cells.

5.1.8.3 Too light or too heavy cell suspension.

5.1.8.4 Improper incubation time or temperature.

5.1.8.5 Calibration of the centrifuge is critical; excessive centrifugation may lead to difficulties in re suspending the cell button, and inadequate centrifugation may yield unclear cell button patterns.

5.1.8.6 Improper examination for agglutination (usually too vigorous shaking) as it may cause agglutinates to be dispersed.

5.1.8.7 Very weak subgroups (of both A and B) may not be detected by these reagents.

5.1.9 Procedure notes:

5.1.9.1 Test results must be interpreted immediately upon completion of the test.

5.1.9.2 Weak reactions may indicate a subgroup of A or B or a mixed population of cells.

5.1.9.3 To solve ABO discrepancies, refer to ABO Discrepancy Solving Procedure.



TITLE: ABO Grouping tube method (Forward Grouping).

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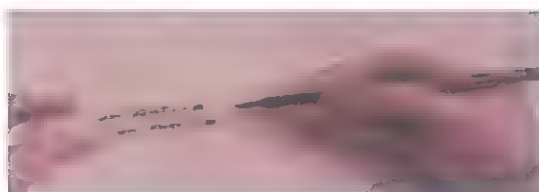
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APPLIES TO: Transfusion Service Laboratory staff.

Procedure for forward grouping.



Step 1: Label test tubes.



Step 2: Make a 2-5% patient red cell suspension.



Step 3: Add reagent antisera as per manufacturer's package insert.



Step 3A: Add reagent Anti-A antisera as per manufacturer's package insert.



Step 3B: Add Anti-B reagent antisera as per manufacturer's package insert.



TITLE: ABO Grouping tube method (Forward Grouping).

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APPLIES TO: Transfusion Service Laboratory staff.



Step 4: Add one drop of 2-5% suspension of patient red cells to each tube.



Step 5: Mix and centrifuge (approximately 20 seconds).



Group B

4+ Agglutination with Anti-B

0 Agglutination with Anti-A



Group A

4+ Agglutination with Anti-A

0 Agglutination with Anti-B



TITLE: ABO Grouping tube method (Forward Grouping).

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APPLIES TO: Transfusion Service Laboratory staff.



Group AB

4+ Agglutination with Anti-A and Anti-B



Group O

No Agglutination with Anti-A or Anti-B

6 Responsibility

6.1 It is the responsibility of assigned technologist/technician work in transfusion service laboratory to follow procedure instruction.

6.2 It is the responsibility of assigned physician assigned in the area to insure implementation of the policy and interpretation of any discrepancy.

7 References:

7.1 Technical Manual American of Blood Banks, 18th edition 2014.

7.2 Guide lines for the blood transfusion services UK 2008.

7.3 Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.






7.4 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.5 CBAHI national standards for hospitals 3rd edition, 2015.



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| TITLE: ABO Grouping tube method (Forward Grouping). | | | |
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| APPLIES TO: Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|--------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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|---|---------------------------------------|--------------------------------------|------------------------------|
| TITLE: ABO Confirmation Testing By Tube Method (Reverse Grouping). | | | |
| EFFECTIVE DATE 04- 06 -2018 | REVISION DATE: 03- 06- 2020 | INDEX NO: APP-LB-BB-11 -V1 | NUMBER OF PAGES: 6 |
| APPLIES TO: Transfusion Service Laboratory staff. | | | |

1. Statement of Purpose

The purpose of this policy to provide guidance to transfusion service laboratory staff to determine ABO Confirmation Testing by tube method (Reverse Grouping) smoothly and in a correct way.

2. Definition

2.1 Accuracy of a measurement system is the degree of closeness of measurements of a quantity to that quantity's actual (true) value.

2.2 Agglutination is clumping of red blood cells in the presence of an antibody.

3. Equipment /Material /Forms :

3.1 For all transfusion service testing, a full 7ml lavender top vacutainer tube (EDTA) is required. A minimum of 3ml from adults, 2ml from pediatric and 1ml from neonates can be accepted.

3.2 Patients Transfusion Request / registration log book .

3.3 Materials:

3.3.1 0.9% normal saline.

3.3.2 A₁ cells.

3.3.3 B cells.

3.3.4 12x75mm test tubes.

3.3.5 Plastic pipettes.

3.3.6 Centrifuge.



| | | | |
|--|--|---|-------------------------------------|
| <u>TITLE:</u> ABO Confirmation Testing By Tube Method (Reverse Grouping). | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-11 -V1 | <u>NUMBER OF PAGES:</u> 6 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

4. Policy Statement:

4.1 It is the policy of transfusion service lab to perform reverse ABO group for all PRBCs units, samples recipients **but not** for infants less than 4 months of age.

4.2 Any discrepancy between forward and reverse grouping shall be solved before result issuing

4.3 It is the policy of transfusion service lab to determine the presence or absence of ABO antibodies to validate the correctness of the forward (antigen) typing. ABO serum confirmation testing utilizes the reactions of known group A₁ and B cells with unknown serum, and compares them to the reactions obtained from the forward typing.

4.4 It is the policy of transfusion service lab to perform tube method for ABO blood grouping by observing for agglutination or hemolysis. Absence of agglutination is a negative test result while presence of agglutination or hemolysis of red cells is a positive test result (see table below). Testing is performed at room temperature.

5.0 Procedure

5.1 Label one tube for each of the Serum Grouping Cells (A₁ and B cell tubes).

5.2 Add two drops of the serum or plasma to be tested to each of the tubes.

5.3 Re-suspend the reverse grouping cells in each vial by inverting several times.

5.4 Add one drop of the re-suspended cells to the appropriately labeled tubes and mix.



TITLE: ABO Confirmation Testing By Tube Method (Reverse Grouping).

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APPLIES TO: Transfusion Service Laboratory staff.

5.5 Centrifuge the tubes for a time appropriate for the centrifuge being used (refer to the latest centrifuge settings).

5.6 Examine the tubes for hemolysis. Record hemolysis if observed.

5.7 Re-suspend the cell button by shaking gently. Examine immediately for agglutination. Record results.

5.8 Interpretation.

| | | |
|----|---|---|
| O | + | + |
| A | 0 | + |
| B | + | 0 |
| AB | 0 | 0 |

5.9 When a new patient sample arrives and a difference in interpretation of the results is observed, proceed with the following.

5.10 Limitations for tube method and Procedure Notes: refer to ABO grouping by tube method (forward grouping) Procedure.

If the new sample confirms the original blood group:

1. *Accept the result.*
2. *Generate OVA and attach a copy of the laboratory request form.*
3. *Refer the issue to the lab director.*

If the new sample confirms the new blood group:

1. *Change the historical blood group.*
2. *Write your comment as follow : (on DD/MM/YYYY, patient ABO/Rh was on DD/MM/YYYY, the patient's ABO/Rh found to be).*
3. *Generate OVA and attach a copy of the laboratory request form.*
4. *Refer the issue to the lab director.*



TITLE: ABO Confirmation Testing By Tube Method (Reverse Grouping).

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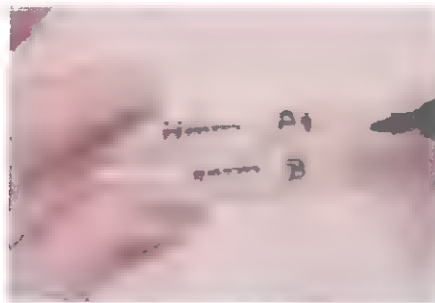
APP-LB-BB-11 -V1

NUMBER OF PAGES:

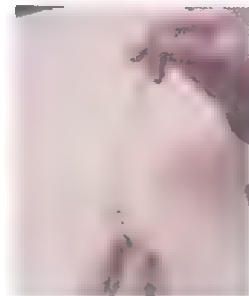
6

APPLIES TO: Transfusion Service Laboratory staff.

Figures of ABO Grouping By Tube Method (Reverse Grouping).



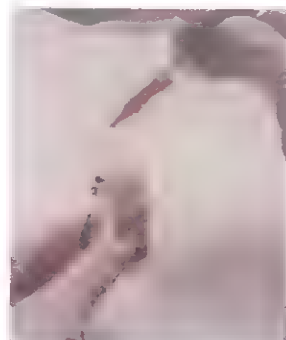
Step 1: Label Test Tubes.



Step 2: Add two drops of patient serum to each tube.



Step 3: Add one drop of reagent cells* to each test tube.



Step 3A: Add one drop of Reagent A+ cells.



Step 3B: Add one drop of Reagent B+ cells.



Step 4: Mix and centrifuge (approximately 20 seconds).



| | | | |
|--|--|---|-------------------------------------|
| <u>TITLE:</u> ABO Confirmation Testing By Tube Method (Reverse Grouping). | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

6.0 Responsibility

6.1 It is the responsibility of assigned technologist/technician work in transfusion service laboratory to follow procedure instruction.

6.2 It is the responsibility of assigned physician assigned in the area to insure implementation of the policy and interpretation of any discrepancy.

7.0 References :

7.1 Technical Manual American of Blood Banks, 18th edition 2014.

7.2 Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.





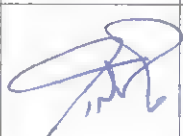
7.3 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.4 CBAHI national standards for hospitals 3rd edition, 2015.



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| TITLE: ABO Confirmation Testing By Tube Method (Reverse Grouping). | | | |
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| APPLIES TO: Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|--------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



TITLE: Rh Grouping And Weak D Testing By Tube Method.

EFFECTIVE DATE

04- 06 -2018

REVISION DATE:

03- 06- 2020

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APPLIES TO: Transfusion Service Laboratory staff.

1. Statement of Purpose

The purpose of this policy is to provide guidance to transfusion service laboratory staff to determine the Rh grouping including weak D smoothly and in a correct way.

2. Definitions:

2.1 Accuracy of a measurement system is the degree of closeness of measurements of a quantity to that quantity's actual (true) value.

2.2 Agglutination is clumping of red blood cells in the presence of an antibody.

3. Equipment /Material /Forms :

3.1 For all transfusion service testing, a full 7ml lavender top vacutainer tube (EDTA) is required. A minimum of 3ml from adults, 2ml from pediatric and 1ml from neonates can be accepted.

3.2 Patients Transfusion Request / registration log book.

3.3 Materials:

3.3.1 0.9% normal saline.

3.3.2 Monoclonal Anti-D.

3.3.3 Rh control.

3.3.4 Anti-IgG.

3.3.5 Coombs Control Cells.

3.3.6 12x75mm test tubes.

3.3.7 Plastic pipettes.



| | | | |
|---|--|--|-------------------------------------|
| <u>TITLE:</u> Rh Grouping And Weak D Testing By Tube Method. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

3.3.8 Centrifuge.

3.3.9 Agglutination viewer.

4. Policy Statement:

- 4.1**It is the policy of transfusion service lab to perform Rh group for PRBCs unit's components, all recipients including infants less than 4 months of age.
- 4.2**It is the policy of transfusion service lab to determine Rh group by testing the red cells for the presence or absence of Rh (D) antigen.
- 4.3**It is the policy of transfusion service lab to perform Rh grouping by observing agglutination or hemolysis.
- 4.4**It is the policy of transfusion service lab to perform weak D tests for indicated cases who show negative Rh grouping results and requested by treating physician.

5. Procedure

- 1.1**Place 1 drop of Anti-D in Control tube.
- 1.2**Add 1 drop of an approximate 3-4% suspension of the red blood cells to be tested to the tube.
- 1.3**Mix thoroughly by shaking.
- 1.4**Centrifuge for the time appropriate to the calibration of the centrifuge (refer to the latest centrifuge settings).
- 1.5**Examine for the absence of hemolysis and then re-suspend the cells by gentle shaking.



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1.6 Read macroscopically for agglutination and record test results.

1.7 If the test result is negative or doubtful and a test for weak D is required, proceed to carry out the test for weak D.

1.8 Test for weak D

1.8.1 The same D tube can be utilized directly for the weak D testing by adding an additional drop of anti-D.

1.8.2 Label a second tube as control and add one drop of patient cells and one drop of Rh control reagent.

1.8.3 Incubate the test and control tubes for 15 minutes at 37°C.

1.8.4 Centrifuge for the time appropriate to the calibration of the centrifuge (refer to the latest centrifuge settings).

1.8.5 Examine for the absence of hemolysis and then re-suspend the cells by gentle shaking.

1.8.6 Read macroscopically for agglutination and record test results.

1.8.7 If definite macroscopic agglutination is observed it is unnecessary to continue. The test cells are D positive.

1.8.8 Wash the cells showing a negative or doubtful result at least 3 times with normal saline, being careful to decant the saline between washes and to re-suspend the cells thoroughly when adding saline for the next wash.

1.8.9 Decant the saline completely following the last wash.

1.8.10 To each tube add 2 drops of Anti- IgG.



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1.8.11 Mix thoroughly, and centrifuge for the time appropriate to the calibration of the centrifuge (refer to the latest centrifuge settings).

1.8.12 Read macroscopically for agglutination and record test results.

1.8.13 An initial negative reaction at the antiglobulin phase of the test for weak D should be controlled after the first reading by the addition of Coombs Control Cells, re-centrifugation and reading again.

1.8.14 **Limitations and Procedure Notes:** Failure to wash the red cells adequately or subsequent contamination of the washed red cells with human protein before testing may cause false negative reactions. Also refer to Limitations of ABO grouping by tube method (forward grouping) Procedure.

6. Responsibility

6.1 It is the responsibility of assigned technologist/technician work in transfusion service laboratory to follow procedure instruction.

6.2 It is the responsibility of assigned physician assigned in the area to insure implementation of the policy and interpretation of any discrepancy

7. References :

7.1 Technical Manual American of Blood Banks, 18th edition 2014.

7.2 Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.






7.3 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.4 CBAHI national standards for hospitals 3rd edition, 2015.



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| APPLIES TO: Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|--------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE:</u> Blood Grouping And Rh Factor By ID Gel Card. | | | |
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1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform blood Grouping and Rh factor by ID Gel Card.

2. Definitions:

2.1. Forward Blood Grouping (Cell Typing) is the testing of red cell suspensions of unknown group to determine the presence or absence of A and/or B antigens using known reagent anti sera.

2.2. Reverse Blood Grouping (Serum Typing) testing the unknown serum/plasma to determine the presence or absence of antibodies corresponding to the A or B antigens lacking on the red cells using known A and B cells.

3. Equipment/Material/Forms:

- 3.1.** EDTA Blood Specimen.
- 3.2.** ID-Card "DiaClon ABO/D+Reverse Card.
- 3.3.** ID-Diluent 2: modified LISS for red cell suspensions.
- 3.4.** ID-Dispenser.
- 3.5.** ID-Pipetor.
- 3.6.** ID-Tips (pipetor tips).
- 3.7.** Test Tubes.
- 3.8.** ID-Working table.
- 3.9.** ID-Centrifuge.



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4. Policy Statement:

- 4.1. It is the policy of transfusion service lab not to release any blood group result without testing cell typing for ABO/Rh grouping and reverse typing for ABO other than infants under 4 Months .
- 4.2. It is the policy of transfusion service lab not to release any blood group result without testing if reaction with Anti A or B is less than 3+ without resolving it.
- 4.3. It is the policy of transfusion service lab to perform weak Rh testing for all donor's specimen if the direct test Rh test is negative and don't do for the patient's specimens.
- 4.4. It is the policy of transfusion service lab to resolve the problem if negative control test is positive before issuing the result.
- 4.5. It is the policy of transfusion service lab to resolve the problem if there is a discrepancy between forward and reverse grouping before issuing the result.

5. Procedure

5.1. Principal

5.1.1. Antigen Antibody Reaction occurs when the particular antigen, is mixed with relevant antibody, antigen can be detected or vice versa by agglutination (clumping) of the antigen.

5.1.2. ID Gel: The ID Gel-system works on a specific gel matrix (Syphacril gel) with different sizes of gel particles for different



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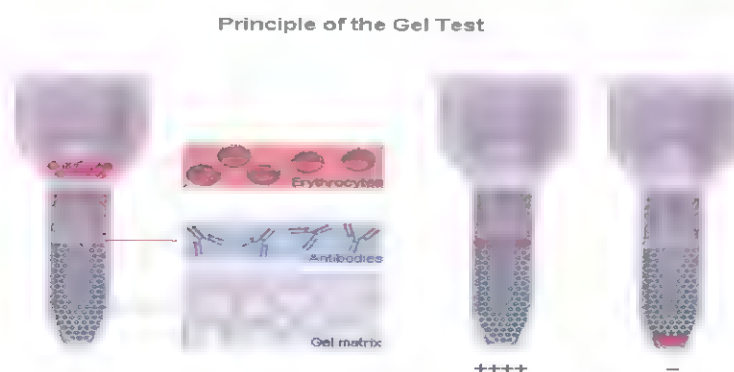
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trapping grades of RBCs. At the beginning of the centrifugation the gel will act as a specific reagent and then, during the centrifugation, as a trapping system.



5.2. Procedure Steps

- 5.2.1. For patient samples check all the items on request and blood specimen, specially the identities must be same.
- 5.2.2. For blood donor specimens check the donation number.
- 5.2.3. Centrifuge the specimen for 5 minutes at 3000 rpm.
- 5.2.4. Label ID ABO/D reverse card and test tube for cell suspension according to blood donor number or patient's sample number.
- 5.2.5. Hold the card up right and remove the aluminum foil.
- 5.2.6. Pipette the cell suspension and plasma as shown in picture below:



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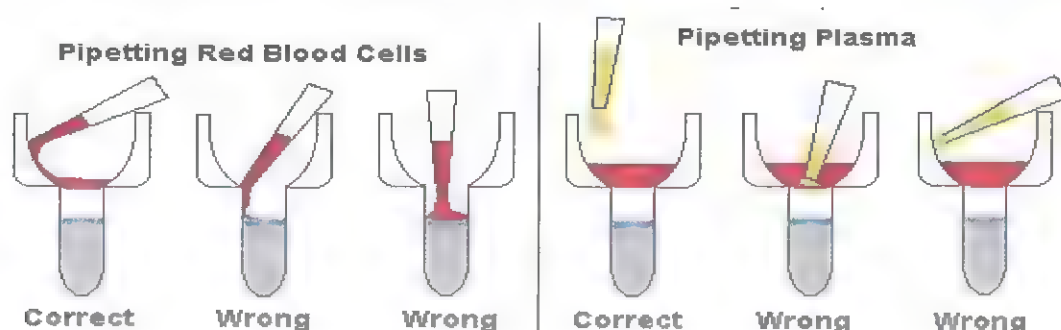
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5.2.7. Pipette 50ul of ID DiaCell A to micro tube A1.

5.2.8. Pipette 50ul of ID DiaCell B to micro tube B.

5.2.9. Pipette 50ul patient plasma (exceptionally Serum) to microtube (5 & 6) A1 and B.

5.2.10. Prepare patients cell 5% suspension

- Dispense 0.5 ml ID Diluent II to a labeled test tube.
- Add 25ul of PRBC (50ul whole blood exceptionally, if need arise) from the centrifuged patient sample tube into diluent and mix.

5.2.11. Pipette 10 or 12.5ul of the patient's cell suspension to the Micro tube (1-4) A, B, D and ctl.

5.2.12. Centrifuge the card for 10 minutes.

5.2.13. Let centrifuge stop, take out the card, read and record the result.



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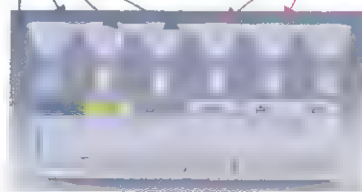
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1. Make a cell suspension (5%) by adding 500ul of diluents² with 25ul of packed cells (from donor unit segment or patient sample) .
2. Dispense as shown then centrifuge for 10 minutes .

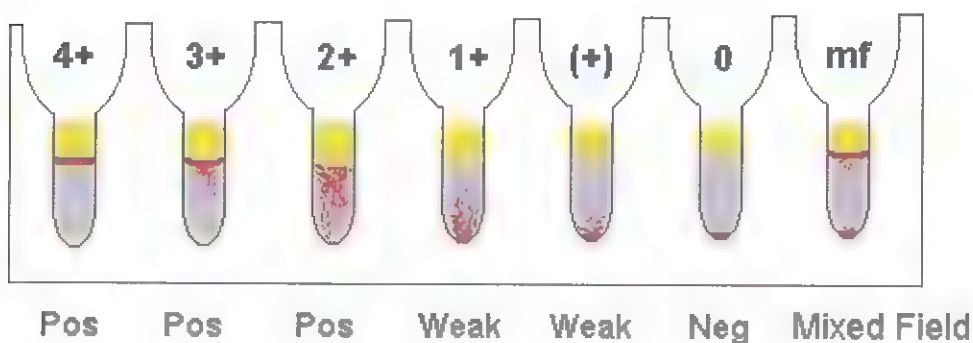
12.5ul of cell suspension

50ul A1 and B cells + 50ul of plasma cells



5.3.Interpretation:

5.3.1. Interpret agglutination as follows





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5.3.2. For weaker reaction less than 3+ proceed to ABO/Rh Discrepancy policy.

5.3.3. Interpret ABO Grouping according to following table.

| Anti A | Anti B | Control | A Cells | B Cells | ABO Group |
|----------|----------|----------|----------|----------|-----------|
| 3+ to 4+ | Negative | Negative | Negative | 1+ to 4+ | A |
| Negative | 3+ to 4+ | Negative | 1+ to 4+ | Negative | B |
| Negative | Negative | Negative | 1+ to 4+ | 1+ to 4+ | O |
| 3+ to 4+ | 3+ to 4+ | Negative | Negative | Negative | AB |

5.3.4. Interpret Rh according to following table

| Anti D | Control | Rh |
|----------|----------|----------|
| 3+ to 4+ | Negative | Positive |
| Negative | Negative | Negative |

5.3.5. Write result.

5.3.6. For Rh Negative result writing follow weak Rh testing policy

5.4. Precautions

5.4.1. Do not use ID-Cards which show signs of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper part of the microtubes or on the underside of the aluminum foil.

5.4.2. Bring ID diluent to room temperature before starting the work.

5.4.3. Pipette cell and serum as shown in the picture.



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5.5.Limitations of procedure.

- 5.5.1.** Bacterial or other contamination of materials used can cause false positive or false negative results.
- 5.5.2.** Fibrin residues in the red cell suspension may trap non-agglutinated cells presenting a fine pink line on top of the gel while most of the cells are on the bottom of the micro tube after centrifugation.
- 5.5.3.** Use of suspension solutions other than ID-Diluent 2 may modify the reactions.
- 5.5.4.** Too heavy or too weak red cell suspensions can cause aberrant results.

6. Responsibility:

- 6.1** It is the responsibility of assigned technologist/technician work in transfusion service laboratory to follow procedure instruction accurately.
- 6.2** It is the responsibility of assigned physician assigned in the area to insure implementation of the policy and interpretation of any discrepancy

7. References:

- 7.1.** Leaflet from DiaMed for ID ABO/D +Reverse (Monoclonal) Blood Grouping Card
- 7.2.** Pictures provided by DiaMed for accurate pipetting procedure and grading the reactions.



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APPLIES TO: Transfusion Service Laboratory staff.

7.3. Technical Manual American of Blood Banks, 18th edition 2014.

7.4. Standards for Blood Bank and Transfusion Services .Bethesda, MD:
American Association of Blood Bank 30th edition, 2016.






7.5. The unified Practical Manual for Blood Banks in Arab Countries
(MOH) 2013.

7.6. CBAHI national standards for hospitals 3rd edition, 2015.



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| APPLIES TO: Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|--------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. **Statement Of Purpose:**

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform weak d test correctly.

2. **Definitions**

2.1 Weak D Antigen: Weak Expression of “D” Antigen on an individual’s RBC which cannot be detected by direct testing by Anti D Sera and it requires AHG test to identify its presence due to fewer D antigen sites per RBC.

2.2 Du Test: An old term to describe red cells that were “D” positive, but which were not agglutinated by Anti D in routine or in other word it is a test detect weak/partial expression of D antigen on human red blood cells. **The current term is Weak D test.**

2.3 Partial D Antigen: RBC having “D” Antigen but missing one or more epitopes of D Antigen. Individual having such RBC may produce allo anti D, if exposed to relevant D+ epitope/s. They are usually typed when an Rh (D) positive individual shows Rh antibodies.

2.4 Rh_{null}: The red cells which do not possess any Rh antigen D, E, C, c or e.

3. **Equipment/Material/Forms:**

3.1. EDTA Blood Specimen.

3.2. ID-Card “DiaClon Liss Coombs Mono Specific (IgG) Cards.



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- 3.3. ID Anti D.
- 3.4. ID-Diluent 2: modified LISS for red cell suspensions.
- 3.5. ID-Dispenser.
- 3.6. ID-Pipetor.
- 3.7. ID-Tips (pipetor tips).
- 3.8. Test Tubes.
- 3.9. ID-Working table.
- 3.10. ID-Centrifuge.

4. Policy Statement:

- 4.1. It is the policy of transfusion service lab to perform weak D test for **all donor' units samples** for blood grouping whose D antigen status is Negative by direct testing (Manual or Gel Cards), less than +3 by Gel or less than +2 by manual tube test.
- 4.2. It is the policy of transfusion service lab to perform weak D test for all neonatal blood samples for blood group testing whose D antigen status is Negative by direct testing (Manual or Gel Cards).
- 4.3. The result shall be written as Rh Weak Positive and in the remarks it shall be noted that the patient must be transfused Rh Negative blood products if required and Rho GAM must be administered to Rh Negative mother if her baby's Rh is Weak Positive.



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5. Procedure

5.1. Principal

5.1.1. Weak/Partial impression of D antigen on the red cells which is not detect by direct testing is incubated at 37°C and tested by coombs serum to enhance the reaction so if these antigens are present they cause agglutination.

5.2. Procedure Steps

5.2.1. Allow the test cell reagents and samples to reach room temperature before use.

5.2.2. Check all blood specimens and their identity (Patient's three names and patient's file number or donor's number).

5.2.3. Prepare 0.8% patient Cell suspension.

- Label test tubes to prepare cell suspension.
- Dispense 1 ml diluent in test tube.
- Dispense 12.5 ul packed red blood cells or 25 ul of whole blood from the specimen.

5.2.4. Label Mono Specific IgG or Liss Coombs Card accordingly.

5.2.5. Dispense 50 ul of cell suspension to each test microtube.

5.2.6. Dispense 50 ul of ID Anti D in the well.

5.2.7. In the figure below:



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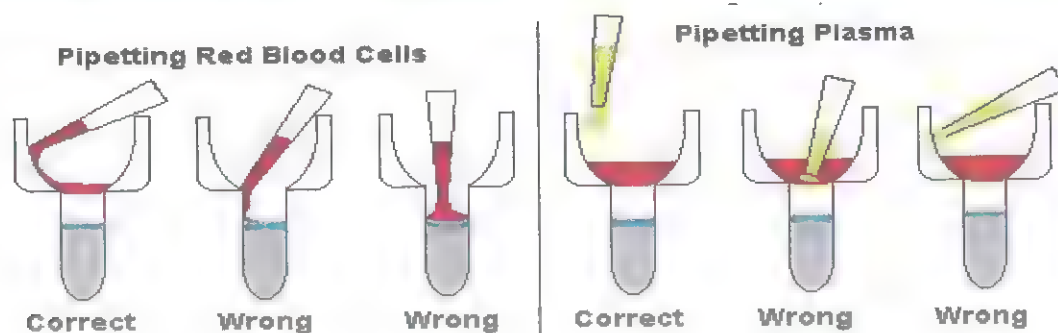
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5.2.8. Incubate the card at 37°C for 15 minutes.

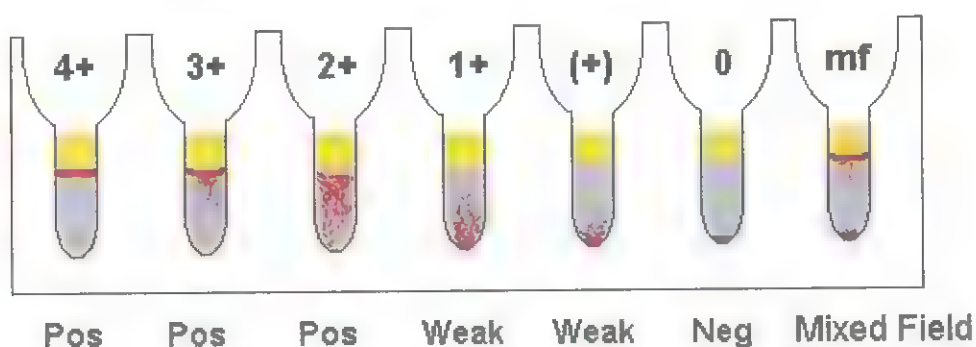
5.2.9. Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.

5.2.10. Let centrifuge stop, take out the card, read and record the result.

5.2.11. Control performs DAT for all samples under test.

5.3. Interpretation:

5.3.1. Interpret agglutination as follows





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5.4. Interpretation of results

| ID Anti D | DAT | Result (Rh) |
|---------------------------|----------|--------------------|
| + to +4 | Negative | **Rh Weak Positive |
| + to +4 | Positive | *Invalid |
| Negative | Negative | Negative |
| Mix Field-two populations | Negative | *** Invalid |

* Perform gentle heat elution and repeat the test when DAT becomes negative.

**Blood donor unit must be labeled as RH positive.

***Mixed field for neonates index for feto-maternal hemorrhage check or RH incompatible transfusion. do not confuse mixed field with + or ++ reactions.

5.5. Precautions

5.5.1. Do not use ID-Cards which show signs of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper part of the microtubes or on the underside of the aluminum foil.

5.5.2. Bring ID diluent to room temperature before starting the work.

5.6. Limitations of procedure

5.6.1 Certain drugs are known to cause positive reactions in anti-human globulin procedures.

5.6.2 Some pathological conditions are also reported as causing positive reactions in anti-human globulin procedures.

5.6.3 Bacterial or other contamination of materials used can cause false positive or false negative results.



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5.6.4 Fibrin residues in the red cell suspension may trap non-agglutinated cells presenting a fine pink line on top of the gel while most of the cells are on the bottom of the microtube after centrifugation.

6. Responsibility:

- 6.1.** It is the responsibility of staff (Assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately.
- 6.2.** It is the responsibility of physician assigned in the area to assure implementation of policies and procedure.






7. References:

- 7.1.** Technical Manual of American Association of Blood Banks, 18th edition 2014.
- 7.2.** Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.
- 7.3.** Leaflet from DiaMed for ID Liss Coombs Cards and ID Anti D.
- 7.4.** Pictures provided by DiaMed for accurate pipetting procedure and grading the reactions.
- 7.5.** Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.
- 7.6.** The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.7.** CBAHI national standards for hospitals 3rd edition, 2015.



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| APPLIES TO: Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 14-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



TITLE: : ABO And Rh Grouping For Infant Below 4 Months By Gel Card.

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APPLIES TO: Transfusion Service Laboratory staff.

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform blood grouping and Rh factor by Id gel card for infant below 4 months.

2. Definitions

2.1. Direct Anti Human Globulin Test (DAT) a test to detect in vivo sensitization of red blood cells by an antibody/Complement or medicine.

2.2. Neonatal Blood Group: Infants less than 3 to 6 months of age lack detectable ABH anti bodies. ABH anti bodies present at birth are passively acquired from the mother.

3. Equipment/Material/Forms:

3.1. EDTA Blood Specimen.

3.2. ID-Card "DiaClon Neonatal Cards.

3.3. ID-Diluent 2: modified LISS for red cell suspensions.

3.4. ID-Dispenser.

3.5. ID-Pipetor.

3.6. ID-Tips (pipetor tips).

3.7. Test Tubes.

3.8. ID-Working table.

3.9. ID-Centrifuge.



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APPLIES TO: Transfusion Service Laboratory staff.

4. Policy Statement:

- 4.1.** Reverse grouping shall not be performed for neonatal samples (up to the age of 4 months).
- 4.2.** If Rh direct test is Negative , weak Rh test (Du) shall be performed for all neonatal samples
- 4.3.** If Rh direct test is less than 3+ the sample shall be further tested for weak Rh testing .
- 4.4.** If Negative Control reveals positive result shall not be released until the discrepancy is solved.
- 4.5.** Direct Coombs test shall be performed and reported for all neonatal samples to know if the infant's cells are coated with maternal antibodies.

5. Procedure

5.1.Principal: refer to ABO and RH grouping by gel card procedure.

5.2.Procedure Steps:

- 5.2.1.** For Patient samples check all the entries on request and blood specimen, specially the identities must be same
- 5.2.2.** Label ID Neonatal card and test tube for cell suspension.
- 5.2.3.** Prepare the cell suspension as below
 - 5.2.3.1.** Dispense 1.0 ml ID Diluent II to a labeled test tube
 - 5.2.3.2.** Add 12.5ul of PRBC (25ul whole blood exceptionally, if need arise) from the patient sample tube into diluent and mix
- 5.2.4.** Hold the card up right and remove the aluminum foil



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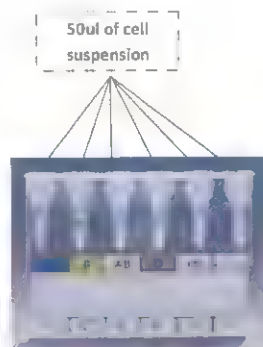
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5.2.5. Pipette 50 ul the patient's cell suspensions to the Micro tube (1-6) A, B, AB, D, Control DAT.

5.2.6. Centrifuge the card for 10 minutes

5.2.7. Let centrifuge stop, take out the card, read and record the result.

1. Make a cell suspension (8%) by adding 1000ul of diluents 2 with 12.5ul of packed cells.
2. Dispense as shown below then centrifuge for 10 minutes.



5.3.Interpretation:

5.3.1. Interpret ABO Grouping according to following table

| Anti A | Anti B | Anti AB | Control | ABO Group |
|----------|----------|----------|----------|-----------|
| 1+ to 4+ | Negative | 1+ to 4+ | Negative | A |
| Negative | 1+ to 4+ | 1+ to 4+ | Negative | B |
| Negative | Negative | Negative | Negative | O |
| 1+ to 4+ | 1+ to 4+ | 1+ to 4+ | Negative | AB |



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5.3.2. Interpret Rh according to following table

| Anti D | Control | Rh |
|----------|----------|-----------|
| 3+ to 4+ | Negative | Positive |
| Negative | Negative | *Negative |

* Proceed to weak Rh testing policy if for conditions other than blood transfusion.

5.3.3 Interpret DAT according to following table

| DAT | Control | RESULT |
|----------|----------|----------|
| Negative | Negative | Negative |
| ± to 4+ | Negative | Positive |

5.3.4 Write result as: example; (Group O Positive).

5.3.5 Write result of DAT as (DAT Positive) or (DAT Negative).

5.3.6 For Rh less than 3+ Proceed to weak Rh testing policy.

5.4 Precautions & Limitations of procedure refer to ABO and RH grouping by gel card procedure.

6. Responsibility:

6.1. It is the responsibility of staff (Assigned technician or technologist) in cross-match room to perform blood group accordingly.

6.2. It is the responsibility of physician assigned in transfusion service laboratory to supervise all the work.



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7. References:

- 7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014
- 7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.
- 7.3. Leaflet from DiaMed for ID Neonatal Blood Grouping Card.
- 7.4. Pictures provided by DiaMed for accurate pipetting procedure and grading the reactions.
- 7.5. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.6. CBAHI national standards for hospitals 3rd edition, 2015.



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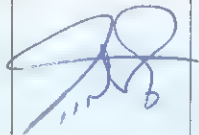
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8. Approvals:

| | Name | Title | Signature | Date |
|--------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12/4/2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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1. Statement of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to solve ABO discrepancy smoothly and without errors.

2. Definitions:

2.1 Accuracy of a measurement system is the degree of closeness of measurements of a quantity to that quantity's actual (true) value.

2.2 ABO discrepancy is a difference in forward and reverse testing found during a blood grouping process when cells and serum testing does not correlates with each other or negative control shows positive reaction.

3. Equipment/Material/Forms:

3.1. EDTA Blood Specimen

3.2. Equipment and material needed for grouping by gel card.

3.3. Equipment and material needed for grouping by tube method.

4. Policy Statement:

4.1. It is the policy of transfusion service lab not to release any blood group result without resolving if reaction in forward or reverse test is equal or less than 2+.

4.2. It is the policy of transfusion service lab to resolve the problem if there is a discrepancy between forward and reverse grouping before issuing the result.



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4.3. It is the policy of transfusion service lab to issue O red cells as the ABO discrepancy is not solved or Rh Negative blood if Rh discrepancy is not solved, if there is a blood component request for that patient.

5. Procedure

5.1. GENERAL GUIDELINES TO RESOLVE ABO DISCREPANCIES

- 5.1.1. Check for clerical/technical errors.
- 5.1.2. Check the patient's age.
- 5.1.3. Check the diagnosis.
- 5.1.4. Check the transfusion history.
- 5.1.5. Re-test.
- 5.1.6. Weakest reaction is usually the one in doubt.
- 5.1.7. Check results of the anti-body screening.

5.2. Check for technical and/or clerical errors.

- 5.2.1. Sample mix-up such as wrong serum tube with wrong clot or 3% suspension.
- 5.2.2. Failure to add serum or reagent can lead to technical errors where no reaction is occurring where one is expected. Remember for both ABO and Rh always add reagent antisera and serum before adding cells.
- 5.2.3. Addition of wrong reagent such as screening cells, which are O, instead of A₁ and B cells, can lead to significant technical errors.



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5.2.4. Contaminated reagents/dried gel in cards could result in either false negative or false positive results.

5.2.5. Under centrifugation or over centrifugation could lead to a negative reaction since the cells are not encouraged adequately to bind with the antibody , or reading the reaction as positive while there is still a button on the bottom of the tube, or your shaking to dislodge the button that may broke up the agglutination reaction.

5.2.6. Warming the test could result in a false negative reaction since ABO antibodies are IgM that react better in the cold.

5.2.7. Too many cells in your cell suspension can lead to decreased or negative reactions since there are too many cells for the number of antibodies present in the reagents. Remember we want to be in the zone of equivalence for our reactions.

5.2.8. Failure to detect weak results.

5.2.9. Failure to detect hemolysis can be a definite problem. Remember a positive reaction can be hemolysis as well as agglutination since the antigen-antibody reaction can bind complement. When complement is bound it can lead to hemolysis that is also an indication of a positive reaction.

5.2.10. Dirty glassware can cause the cells to artificially clump.

5.3. **Repeat the plasma or serum and cell tests first:**

5.3.1. Wash red cells three times with saline.



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5.3.2. Make patient red cell suspension accordingly.

5.3.3. Repeat the testing, following proper technique and interpretation of results.

5.3.4. If the discrepancy still exists, continue with further testing.

5.4. **If the Negative Control (Rh Control) Reveals positive:**

5.4.1. Repeat the test as described above 5.3

- If control reveals negative, release the result.
- If the problem persists consider for cold auto antibodies/stronger rouleaux.
- Check under microscope if it is rouleau or agglutination. If looks rouleau, wash at least 10 times further and repeat.
- If looks agglutination proceed to pre-warm procedure.

5.5. **Weakest reaction is usually the one in doubt.**

5.5.1. RBCs of most A, B, or AB people are strongly agglutinated (+3 - 4+) by the corresponding reagent antibody, and the sera of these usually strongly agglutinate A₁ or B reagent red cells (+2 - 4+).

5.5.2. Check transfusion history for non-type specific transfusions.

5.6. **Check the results of the antibody screen.**

5.6.1. If the result of antibody screen is positive, identify the antibody by panel.

5.6.2. Repeat reverse group with type A₁ and B cells negative for corresponding antigen.



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Note: Presence of IgM alloantibodies such as anti-M, anti-N, anti-Le^a, anti-Le^b, anti-P₁, anti-I or cold auto antibody can result in unexpected positive results in the plasma/serum testing.

5.7. Check the patient's age.

5.7.1. Newborns and elderly patients can have weak or missing reactivity in the plasma/serum testing.

5.8. Check the diagnosis.

5.8.1. Immune deficiencies, leukemia/malignancies, chemotherapy, radiation therapy, and bone marrow transplantation can explain missing reactivity in the forward or reverse type.

5.9. Discrepancy between present and historical type:

5.9.1. If present ABO and Rh test result differs than the historical results, request a new specimen.

5.9.2. If both fresh results are similar, issue result and inform the supervisor to make necessary corrections in the patient file.

5.9.3. If both results of fresh sample differ request a third sample with the remarks that "ABO or Rh (accordingly) Discrepancy exists in both new samples, Please send a new sample from the properly identified patient".

5.9.4. Test the third sample, release the results and inform Technical Supervisor/Medical director write an OVAR.

5.10. Examples of ABO discrepancies and possible resolution



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| | Forward | | Reverse | | Screening Cells | Autocontrol | Possible Causes | Possible Resolution |
|---|---------|--------|----------------------|---------|-----------------|-------------|---|--|
| | Anti-A | Anti-B | A ₁ Cells | B Cells | | | | |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | Group O newborn; elderly patient; low immunoglobulin levels | Incubate test at 4°C, check age of patient. |
| 2 | 4+ | 4+ | 2+ | 2+ | 2+ | 2+ | Rouleaux; cold autoantibody | Wash RBCs and repeat testing; test for cold antibodies. |
| 3 | 4+ | 0 | 1+ | 4+ | 0 | 0 | Probable A ₂ subgroup with anti-A ₁ | Test with anti-A ₁ and anti-H lectins and A ₂ cells. |
| 4 | 3+ | 4+ | 1+ | 0 | 0 | 0 | Probable A ₂ B subgroup with anti-A ₁ | Test with anti-A ₁ and anti-H lectins and A ₂ cells. |
| 5 | 0 | 0 | 4+ | 4+ | 4+ | 0 | Probable O _h (Bombay) | Test with anti-H lectin; may sent to reference lab for confirmation. |
| 6 | 4+ | 2+ | 0 | 4+ | 0 | 0 | Probable acquired B phenotype | Investigate patient history; test with anti-B lectin if available. |
| 7 | 4+ | 4+ | 2+ | 0 | 2+ | 0 | Probable alloantibody | Perform antibody identification (antibody panel) |
| 8 | 0 | 4+ | 4+ | 1+ | 1+ | 1+ | Probable group B with cold autoantibody | Test for cold antibodies and identify if appropriate |

Adapted from Table 3-11; Flynn =, J.C. (1998). Essentials of Immunohematology. Philadelphia: W.B.Saunders Company.



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5.11. REVERSE TYPE:

5.11.1. MISSING OR WEAK REACTIONS

- Immunodeficient patients may not produce detectable levels of anti-A and anti-B. These antibodies are absent from the serum of newborns and may be weak in serum from normal elderly persons. Check the age and diagnosis of the patient.
- Use four drops of the patient's plasma/serum in the reverse typing test that did not give the expected results. Re-spin the tube(s) and examine for agglutination.
- Incubate the same reverse typing tests and an auto control at 1-6°C for 15 - 30 minutes. Spin tubes and examine for agglutination. If the auto control is negative or significantly weaker than the positive test results, the test is valid.

5.11.2. REVERSE TYPE: EXTRA OR UNEXPECTED REACTIONS

(Look for Rouleaux)

- Observe reverse typing tubes under a microscope, looking for the characteristic "coin stacking" appearance of the red cells when rouleaux is present. If rouleaux is present, use **saline replacement** technique to resolve .
- Rouleaux will disperse by saline replacement, whereas true agglutination will remain.
- If true agglutination remains, continue with further testing.



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- d. Type in the comment of how the discrepancy was resolved, such as: saline replacement used.

5.12. Unexpected cold auto/alloantibodies:

5.12.1. Unexpected auto/alloantibodies that react at room temperature, such as Anti-P₁, or Anti-M, may agglutinate the red cells used in plasma/serum tests if patient carries the corresponding antigen. Antibody screen may or may not be positive.

5.12.2. Raise the temperature of the patient plasma/serum to 30° - 37°C before mixing the plasma/serum with the cells in reverse typing. If the thermal optimum of the auto/alloantibody is below the temperature at which Anti-A and Anti-B react, this may resolve the discrepancy.

5.12.3. Use A₁ cells and B cells negative for the corresponding antigens.

- If reagent A and B cells are not available, you may use A and B red cells from any RBC unit that is found to lack the corresponding antigen.
- Washed group A and B cord cells can also be used to obtain valid reactions if a cold antibody is interfering with the reverse type.
- If the antibody screen is negative, test the plasma against



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several examples of A and B red cells. The serum may contain an antibody directed against an antigen of low incidence, which will be absent from most randomly selected A and B red cells.

5.13. Unexpected anti-A₁ in plasma/serum:

5.13.1. Anti-A₁ in the plasma/serum of a subgroup of A or AB will agglutinate the A₁ cells used for reverse grouping. Initial test results may appear at the immediate spin phase:

5.14. SUBGROUP OF A

| Anti-A | Anti-B | Anti-A ₁ | Anti-A,B | A ₁ Cells | A ₂ Cells | B cells | Blood Group |
|--------|--------|---------------------|----------|----------------------|----------------------|---------|-----------------------|
| Pos | Neg | Neg | Pos | Pos | Neg | Pos | A₂ |
| Pos | Pos | Neg | Pos | Pos | Neg | Neg | A₂B |

5.14.1. Check recent transfusion history for group O products, (especially platelets) that would explain the presence of this antibody.

5.14.2. Test the patient's red cells with **anti-A₁ lectin** following manufacturer's directions.

- a. Patients transfused with non-type specific RBCs in the previous 3 months may show a mixed field reaction. Anti-A₁ lectin results should be interpreted with care by comparing to reactions



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obtained with the controls.

- b. If the patient is a subgroup of A or AB, the test with Anti-A₁ lectin will be negative.

5.14.3. If the Anti-A₁ Lectin is negative, test the patient's plasma/serum with A₂ cells. This test should be negative if the patient is a subgroup of A or AB.

| Blood Group | A ₁ Cells | A ₂ Cells | A ₁ Lectin | Anti H |
|----------------------|----------------------|----------------------|-----------------------|----------|
| Group A ₁ | Negative | Positive | Positive | Negative |
| Subgroup of A or AB | Positive | Negative | Negative | Positive |

5.14.4. Compatibility testing with anti-A₁ antibody:

- Select O red cells and issue by immediate spin if anti body screen of the patient is negative.
- Cross match (AHG) A₂ Units, Type A units with anti-A₁ to find non A₁ units.
- Give patient a "Transfuse with O/A₂ red cells only" instruction.
- Enter in the remarks in the computer that patients must take O/A₂ red cells only.
- Notify the blood bank medical director of the situation.

5.15. FORWARD TYPE: MISSING OR WEAK REACTIONS

5.15.1. A or B subgroup:

5.15.2. Incubate washed red cells with anti-A, anti-B and anti-A,B for 30



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minutes at room temperature to increase the association of antibody with the scant amount of antigen.

Note: A_x subgroups often only react with anti-A,B.

5.15.3. Read microscopically for weak agglutination or mixed field.

Note: Mixed-field agglutination is characteristic of the reaction between A₃ red cells & reagent anti-A.

5.16. Adsorption/elution studies, if needed, would be performed.

5.17. Disease (leukemia):

5.17.1. Obtain any clinical history of bone marrow transplant or leukemia.

5.17.2. Incubate washed red cells with anti-A, anti-B and anti-A,B for 30 minutes at room temperature to increase the association of antibody with the scant amount of antigen.

5.17.3. Read microscopically for weak agglutination or mixed field.

5.18. FORWARD TYPE: EXTRA OR UNEXPECTED REACTIONS

5.18.1. Strongly positive DAT:

5.18.2. Wash the cells several times with saline warmed to 37°C.

5.18.3. Re-test the forward type.

5.18.4. If the agglutination is IgM-related and it is not dispersed by this technique, the red cells can be treated with dithiothreitol (DTT).



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5.19. Acquired B:

5.19.1. Check the patient's diagnosis. Acquired B antigens are usually associated with tissue conditions that allow enteric bacteria to enter the circulation, like cancer colon or a gram negative infection.

5.19.2. Test the patient's plasma against autologous red cells. The individual's anti-B will not agglutinate his or her own red cells that carry the acquired B.

5.19.3. Check monoclonal anti-B product insert, some monoclonal antibodies do not react with the acquired B phenotype; this information should be included in the manufacturer's directions.

5.19.4. Transfuse immediate spin cross match compatible type O units. Give patient a "Transfuse with O cells only" instruction in Patient Instructions.

5.20. B (A) phenotype:

5.20.1. B (A) phenotype is an autosomal dominant phenotype characterized by weak A expression on group B red cells.

5.20.2. Check monoclonal anti-A product insert, most cases of B (A) phenotypes have been detected with monoclonal anti-A reagents containing the MHO4 clone.

5.20.3. Testing the sample with a polyclonal anti-A or a different monoclonal anti-A should resolve the discrepancy.



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5.21. Polyagglutination due to T activation:

5.21.1. Check diagnosis for bacterial or viral infections. T-activation is caused by bacteria or viruses that produce the enzyme neuraminidase.

5.21.2. Test the patient's red cells with AB serum from another patient or a donor. They should agglutinate due to anti-T in the AB serum.

5.22. FORWARD TYPE: MIXED FIELD REACTIONS

5.22.1. ABO mismatch Transfusions:

- a. Check transfusion history. Mixed cell populations resulting from transfusion of group O red cells to a non-group-O recipient.
- b. Mixed-field reactions due to transfusion last only for the life of the transfused red cells (120 days)

5.22.2. Bone Marrow Transplant:After bone marrow transplantation, the mixed-field reaction usually disappears when the patient's own red cells are no longer produced. Persistent mixed-cell populations do occur in some bone marrow recipients.



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5.23. BLOOD PRODUCTS ABO DISCREPANCY

5.23.1 If a unit confirmation does not match the ABO with which the unit is labeled, pull another segment from the unit and repeat the ABO confirmation.

5.23.2 Notify the blood bank medical supervisor for the discrepancy, if the discrepancy persists.

5.23.3 Hold the unit till discrepancy is resolved and it is correctly labeled.

5.24 If ABO discrepancy is unresolved, or an A or B subgroup, “Transfuse with O cells only”.

5.25 If an Rh discrepancy is unresolved, “Transfuse with Rh Negative cells only”.

6. Responsibility:

6.1. It is the responsibility of transfusion service lab technician/technologist to perform the job.

6.2. The physician assigned in the transfusion service lab is responsible for observation of proper processing of blood products request.



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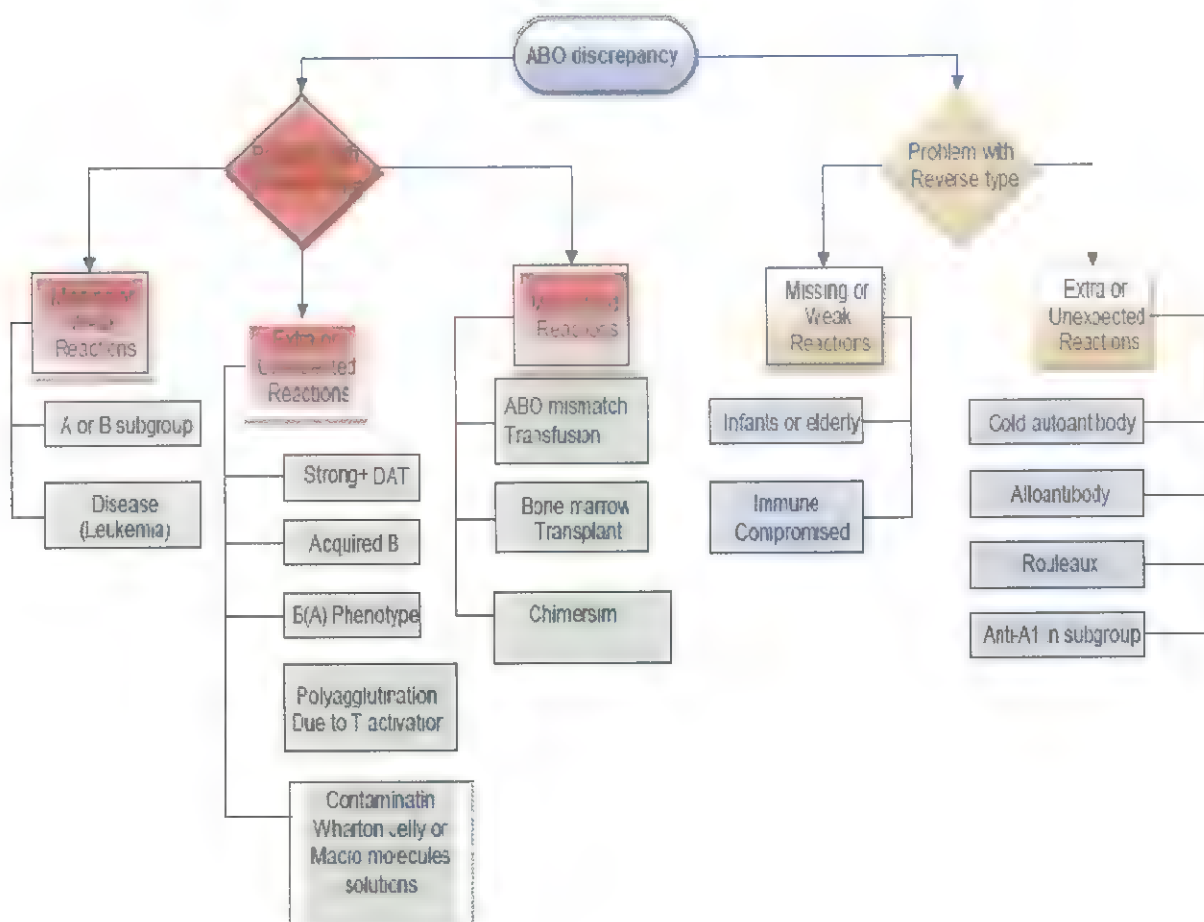
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| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-16-V1 | <u>NUMBER OF PAGES:</u> 17 |
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Flow chart of ABO Discrepancy Solving procedure.





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| <u>TITLE</u> ABO Discrepancy Solving. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



TITLE Anti Body Screening By Tube Method.

EFFECTIVE DATE

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6

APPLIES TO: Transfusion Service Laboratory staff.

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform anti body screening by tube method smoothly in correct way.

2. Definitions

2.1. Antibody Screening: Detection of unexpected (unnatural) antibodies produced against red cell antigen using reagent red cells of known phenotypes by Indirect Anti Human Globulin (ICT).

2.2. Unexpected Antibodies: Antibodies produced in antigenic response other than the naturally occurring A and B antibodies.

3. Equipment/Material/Forms

3.1 For all transfusion service lab testing , a full 7 ml lavender top (EDTA) is required , a minimum of 3 ml from adults , 2 ml from pediatric and 1 ml of neonates.

3.2 0.9 % normal saline.

3.3 LISS or 22% Bovine albumin.

3.4 Antibody Screening Cells (I, II, III) 2-4 %.

3.5 Anti-Human Globulin (AHG).

3.6 Coombs Control Cells.

3.7 12 x75 mm test tubes.

3.8 Plastic Pipettes.

3.9 Centrifuge.



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| <u>TITLE</u> Anti Body Screening By Tube Method. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-17 -V1 | <u>NUMBER OF PAGES:</u> 6 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

- 3.10 Agglutination viewer.
- 3.11 Calibrated cell washer.
- 3.12 Heat Block set at 37 °C.
- 3.13 22% Bovine albumin.
- 3.14 Blood bank registration log book.
- 3.15 Blood transfusion requests.

4.0 Policy Statement:

- 4.1 It is the policy of transfusion service to perform antibody screen test for demonstrating clinically significant red cell antibodies. Agglutination or hemolytic of one or more of the cells indicates the presence of an antibody directed against the corresponding antigen on the red cells.
- 4.2 It is the policy of transfusion service that; to perform blood grouping and antibody screen test for all patients requiring red blood cells transfusion on a specimen collected from the recipient on every admission and within three days of the scheduled transfusion time.
- 4.3 It is the policy of transfusion service to perform antibody screen test for all patients requiring red blood cells transfusion.

4.3.1 Anti-body screening for all patients requiring antibody screen or pre-transfusion compatibility testing shall be performed using 3 cell panel of known phenotype by Indirect Anti Human Globulin test (IAT).



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| <u>TITLE</u> Anti Body Screening By Tube Method. | | | |
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4.3.2 The screening cells shall express at least the following antigens:

D, C, E, c, e, K, k, Fy^a, Fy^b, Jk^a, Jk^b, Le^a, Le^b, Pl, M, N, S,s, Lu^a.Lu^b.

4.4. It is important to check the current antibody screen result with the history of patient antibody screen.

4.5 Transfusion request and sample receiving SOP shall be strictly followed.

5.0 Procedure :

5.1 Allow the test cell reagents and samples to reach room temperature before use.

5.2 Arrange the bench and perform quality control on reagent red cells.

5.3 Check all blood specimen and their identity (Patients three name and patient's number).

5.4 Label tube for each of the screening cells to be used.

5.5 Add 2 drops of the plasma to be tested to each of the tubes.

5.6 Re-suspend the cells in each vial by inverting the vials several times.

5.7 Add one drop from each vial 2-4 % to the appropriately labeled tube.

5.8 Add two drops of LISS or 22% Bovine albumin to each of the test tubes and mix.

5.9 Incubate the test and control tubes for 30 minutes at 37 °C.

5.10 Centrifuge for the time appropriate to the calibration of the centrifuge.

5.11 Examine for the absence of hemolysis and then re- suspend the cells by gentle shaking.

5.12 Read macroscopically for agglutination and record test results.

5.13 Wash the cells showing a negative or doubtful result at least 3 times with physiologic saline, being careful to decant the saline between



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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

washes and re-suspend the cells thoroughly when adding saline for the next wash.

- 5.14 Decant the saline completely following the last wash.
- 5.15 To each tube add 2-3 drops of AHG.
- 5.16 Mix thoroughly and centrifuge for the time appropriate to the calibration of the centrifuge.
- 5.17 Read macroscopically for agglutination and record test results.
- 5.18 A negative reaction at the Antiglobulin phase should be controlled after the initial reading by the addition of Coombs Control Cells, centrifugation and reading again.
- 5.19 Interpretation: When an antibody is detected, its specificity may be determined by testing the plasma with a panel of Reagent Red Blood Cells.
- 5.20 Limitations :False positive or false negative results may occur from :
 - a. Contamination of test materials.
 - b. Improper storage of test materials.
 - c. Improper centrifugation.
 - d. Improper incubation time or temperature.
 - e. Inadequate washing of red cells.
 - f. Omission of Anti- Human globulin or test serum.

6.0 Responsibility:

- 6.1 It is the responsibility of staff (Assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately.
- 6.2 It is the responsibility of assigned physician to assure implantation of policies and procedure.



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| <u>TITLE</u> Anti Body Screening By Tube Method. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |






7.0References:

- 7.1. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.
- 7.2. Technical Manual of American Association of Blood Banks, 18th edition 2014.
- 7.3. Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.
- 7.4. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.5. CBAHI national standards for hospitals 3rd edition, 2015.



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| TITLE Anti Body Screening By Tube Method. | | | |
| EFFECTIVE DATE 04- 06- 2018 | REVISION DATE: 03- 06- 2020 | INDEX NO: APP-LB-BB-17 -VI | NUMBER OF PAGES: 6 |
| APPLIES TO: Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> Anti Body Screening By ID Gel Card. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-18 -V1 | <u>NUMBER OF PAGES:</u> 6 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform anti body screening by ID Gel Card in a correct way.

2. Definitions

- 2.1. Antibody Screening:** Detection of unexpected (unnatural) antibodies produced against Red Cell Antigen using reagent red cells of known phenotypes by Indirect Anti Human Globulin (IAT).
- 2.2. Unexpected Antibodies:** Anti bodies produced in antigenic response other than the naturally occurring A and B antibodies.

3. Equipment/Material/Forms:

- 3.1.** EDTA Blood Specimen.
- 3.2.** ID- Liss Coombs Cards.
- 3.3.** ID-DiaCells 1, 2 and 3.
- 3.4.** ID-Diluent 2: modified LISS for red cell suspensions.
- 3.5.** ID-Dispenser.
- 3.6.** ID-Pipetor .
- 3.7.** ID-Tips (pipetor tips).
- 3.8.** Suspension Tubes.
- 3.9.** ID-Working table.
- 3.10.** ID-Centrifuge.



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| <u>TITLE</u> Anti Body Screening By ID Gel Card. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

3.11. Registration log book.

3.12. Blood transfusion requests.

4. **Policy Statement:**

4.1. It is the policy of transfusion service lab to perform antibody screen test for all patients requiring red blood cells transfusion.

4.1.1. Anti-body screening for all patients requiring antibody screen or pre-transfusion compatibility testing shall be performed using 3 cell panel of known phenotype by Indirect Anti Human Globulin test (IAT).

4.1.2. The screening cells shall express at least the following antigens: D, C, E, c, e, K, k, Fy^a, Fy^b, Jk^a, Jk^b, Le^a, Le^b, P1, M, N, S, s, Lu^a. Lu^b

4.1.3. It is the policy of transfusion service lab that; to perform blood grouping and antibody screen test for all patients requiring red blood cells transfusion on a specimen collected from the recipient on every admission and within three days of the scheduled transfusion time.

4.1.4. It is important to check the current antibody screen result with the history of patient antibody screen.

4.1.5. Transfusion request and sample receiving SOP shall be strictly followed.



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5. Procedure

5.1. **Principal:** refer to ABO and RH grouping by gel card procedure.

5.2. Procedure Steps

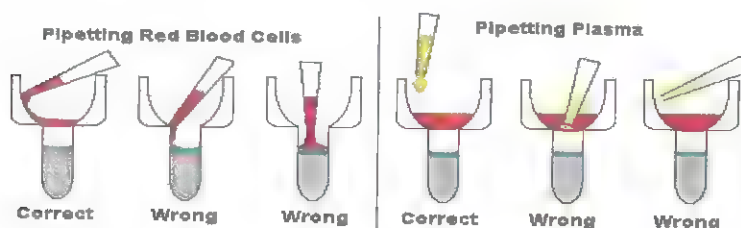
5.2.1. Allow the test cell reagents and samples to reach room temperature before use.

5.2.2. Check all Blood specimen and their identity (Patient's three name and patient's number).

5.2.3. Centrifuge the specimen for 5 minutes at 3000 rpm.

5.2.4. Label ID Liss Coombs cards 3 microtubes for one patient

- Cell 1, 2 and 3 and patient lab number.
- Hold the card up right and remove the aluminum foil.
- Pipette the cell suspension and plasma as shown in picture below .



5.2.5. Pipette 50ul of ID DiaCell 1 to micro tube 1, ID Diacell 2 to microtube number 2 and so on cell 3 to tube 3.

5.2.6. Pipette 25ul of plasma to the labeled three microtubes for that patient.

5.2.7. Incubate the ID-Card for 15 minutes at 37 °C in the ID-Incubator.



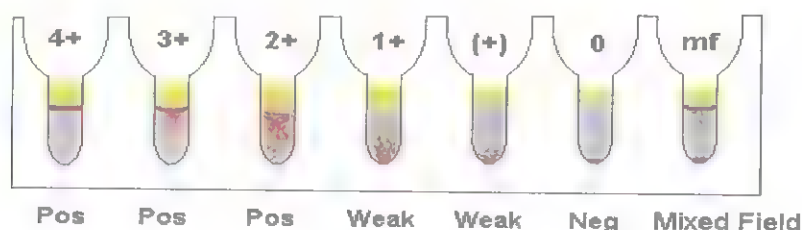
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| <u>TITLE</u> Anti Body Screening By ID Gel Card. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-18 -V1 | <u>NUMBER OF PAGES:</u> 6 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

5.2.8. After incubation Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.

5.2.9. Let centrifuge stop, take out the card, read and record the result.

5.3. Interpretation:

5.3.1. Interpret agglutination as follows



5.3.2. Write the result on your work sheet.

5.3.3. If the test is positive (any of the three cells) perform anti body identification

5.3.4. **Precautions and limitation:** refer to ABO and RH grouping by gel card procedure.

6. Responsibility:

6.1. It is the responsibility of staff (Assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately.

6.2. It is the responsibility of assigned physician to assure implantation of policies and procedure.



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| <u>TITLE</u> Anti Body Screening By ID Gel Card. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |





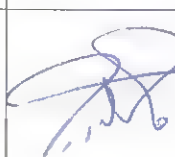
7. References:

- 7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.
- 7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.
- 7.3. Leaflet from DiaMed for ID Liss Coombs Cards.
- 7.4. Pictures provided by DiaMed for accurate pipetting procedure and grading the reactions.
- 7.5. Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.
- 7.6. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.7. CBAHI national standards for hospitals 3rd edition, 2015.



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| <u>TITLE</u> Anti Body Screening By ID Gel Card. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15-4-2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 14-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> Direct Antiglobulin Test (DAT) By Tube Method. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-19 -V1 | <u>NUMBER OF PAGES:</u> 6 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform Direct Antiglobulin Test (Direct Coombs Test) by tube method for its client by an accurate way.

2. Definitions:

2.1. Direct Antiglobulin Test (DAT): A test for detecting in vivo sensitized erythrocytes of patients that's causing auto agglutination of patient's red cells due to IgG or complement.

3. Equipment/Material/Forms:

- 3.1. EDTA Blood specimen.
- 3.2. AHG Coomb's reagent- poly- specific (IgG, C3d).
- 3.3. AHG or Coomb's reagent- Mono specific IgG.
- 3.4. AHG or Coomb's reagent- Mono specific C3, C4.
- 3.5. IgG coated red cells (Coombs Check cells-CCC).
- 3.6. Normal saline (0.9 % NaCl).
- 3.7. Wash Bottle.
- 3.8. Test tubes (12mm x 75mm).
- 3.9. Centrifuge.
- 3.10. Serological Centrifuge.
- 3.11. Marker pen/pencil.
- 3.12. Transfer pipettes.
- 3.13. Registration log book.
- 3.14. Blood transfusion requests.



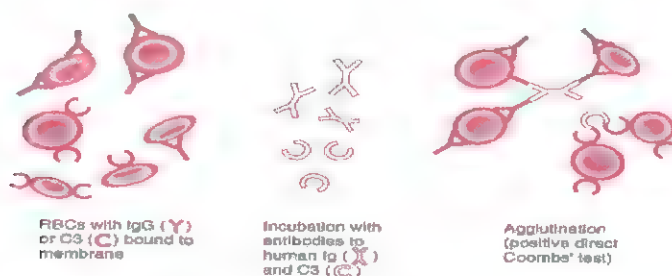
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| <u>TITLE</u> Direct Antiglobulin Test (DAT) By Tube Method. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-19 -V1 | <u>NUMBER OF PAGES:</u> 6 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

4. Policy Statement:

- 4.1. It is the policy of transfusion service lab to perform DAT for all neonates' blood samples, and adults' samples on physicians request or for transfusion reaction investigations.
- 4.2. Transfusion request and sample receiving SOP shall be strictly followed.

5. Procedure

- 5.1. Principal :Anti-Human Globulin (Coombs) serum cause washed red cell to agglutinate in vitro if the cells are sensitized by IgG antibodies or Complement.



5.2. Procedure Steps

- 5.2.1. Allow the test cell reagents and samples to reach room temperature before use.
- 5.2.2. Check all blood specimens and their identity (Patient's names, patient's number).
- 5.2.3. Prepare 3-5% of red cell suspension.
- 5.2.4. Add 1 drop of 3-5% of the prepared red cell suspension and wash it 3 to 4 times at 3400 rpm for 2 minutes for each wash.



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| <u>TITLE</u> Direct Antiglobulin Test (DAT) By Tube Method. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

5.2.5. Completely dry the red cells button by decant the test tube and soak the test tube margins with blotting paper at last wash.

5.2.6. Add 2-3 drops of poly specific AHG to the appropriately labeled tube.

5.2.7. Mix well, centrifuge, resuspend and examine the results macroscopically as well as microscopically for agglutination and record the results.

5.2.8. If negative, incubate at room temperature for 10 minutes, centrifuge, resuspend, and read microscopically and record the results.

5.2.9. To each negative test add one drop of C.C.C. and centrifuge, resuspend, and examine macroscopically or microscopically. If the result is negative, repeat the whole test because the test result is invalid.

5.2.10. If poly specific AHG test is positive perform mono specific AHG IgG, C3 and C4 test according to the procedure above.

5.2.11. Interpretation:

- Immediate or delayed (5-10 mins) agglutination indicates a positive DAT.
- NO agglutination indicates a Negative DAT.



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| <u>TITLE</u> Direct Antiglobulin Test (DAT) By Tube Method. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

6. Responsibility:

- 6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately.
- 6.2 It is the responsibility of assigned physician to assure implementation of policy and procedure.

7. References:

- 7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.
- 7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition
- 7.3. Leaflet from the manufacturer of Coombs serum.
- 7.4. Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.
- 7.5. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.6. CBAHI national standards for hospitals 3rd edition, 2015.



TITLE Direct Antiglobulin Test (DAT) By Tube Method.

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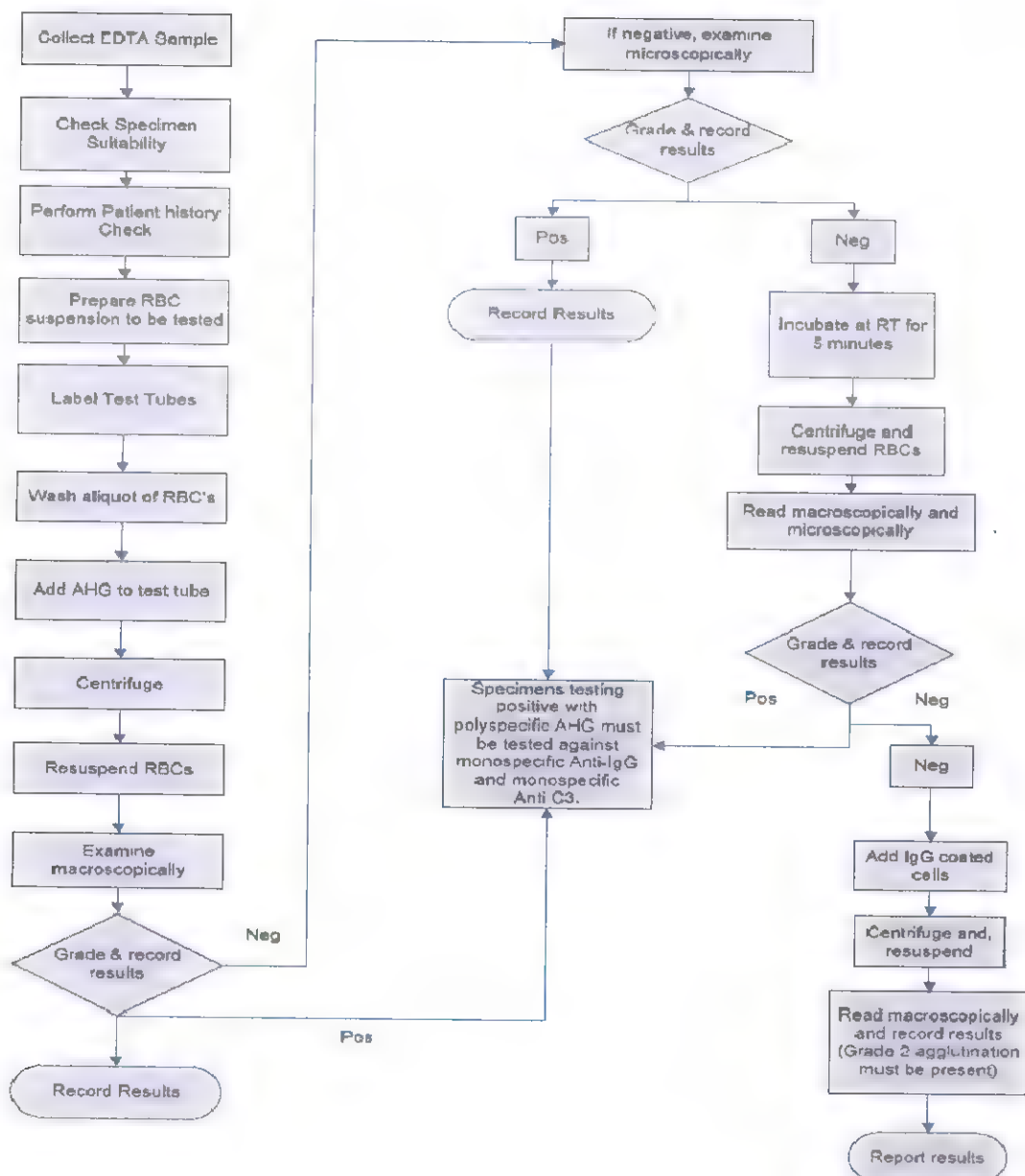
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APPLIES TO: Transfusion Service Laboratory staff.






Process Flow of DAT test.





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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 14-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> Direct Antiglobulin Test (DAT) By Gel Card. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB- 20 -V1 | <u>NUMBER OF PAGES:</u> 5 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service lab staff to perform Direct Antiglobulin Test (Direct Coombs Test) by gel card method for its client by an accurate way.

2. Definitions:

2.1 Direct Antiglobulin Test (DAT): A test for detecting in vivo sensitized erythrocytes of patients that's causing auto agglutination of patient's red cells due to IgG or complement.

3. Equipment/Material/Forms:

- 3.1. EDTA Blood Specimen.
- 3.2. ID-Card "DiaClon Liss Coombs Poly Specific (IgG+C3d) Cards.
- 3.3. ID-Card "DiaClon Liss Coombs Mono Specific (IgG, C3, C4) Cards.
- 3.4. ID-Diluent 2: modified LISS for red cell suspensions
- 3.5. ID-Dispenser.
- 3.6. ID-Pipetor.
- 3.7. ID-Tips (pipetor tips).
- 3.8. Suspension Tubes.
- 3.9. ID-Working table.
- 3.10. ID-Centrifuge.
- 3.11. Registration log book.
- 3.12. Blood transfusion request.



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| <u>TITLE</u> Direct Antiglobulin Test (DAT) By Gel Card. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB- 20 -V1 | <u>NUMBER OF PAGES:</u> 5 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

4. **Policy Statement:** refer to DAT by tube method policy statement.

5. **Procedure:**

5.1. **Procedure Steps**

5.1.1. Allow the test cell reagents and samples to reach room temperature before use.

5.1.2. Check all blood specimen and their identity (Patient's names, patient's number).

5.1.3. Prepare 0.8% patient Cell suspension.

- Label test tube/s to prepare cell suspension.
- Dispense 1 ml diluent 2 in test tube.
- Dispense 12.5 ul packed red blood cells or 25 ul of whole blood from the specimen.

5.1.4. Label Poly Specific Liss Coombs Card accordingly.

5.1.5. Dispense 50 ul of cell suspension to each test microtube.

5.1.6. Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.

5.1.7. Let centrifuge stop, take out the card, read and record the result.

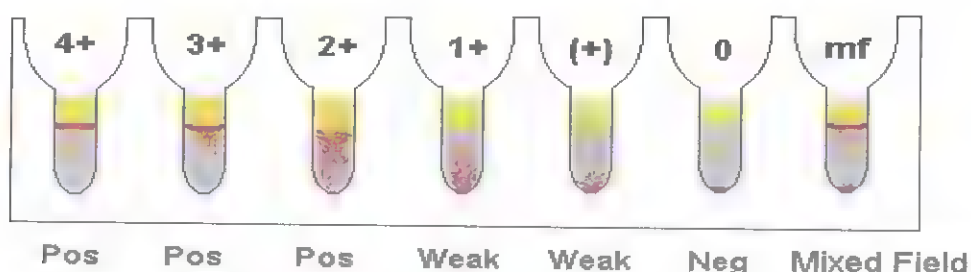
5.1.8. If the DAT is Positive re-perform the procedure by AHG IgG mono-specific, AHG C3 and C4 and report accordingly.



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| APPLIES TO: Transfusion Service Laboratory staff. | | | |

5.2. Interpretation:

5.2.1. Interpret agglutination as follows



5.2.2. RESULT:

5.2.3. DAT= POSITIVE. OR DAT= NEGATIVE .

5.3. Precautions

5.3.1. Do not use ID-Cards which show signs of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper part of the microtubes or on the underside of the aluminum foil.

5.3.2. Bring ID diluent to room temperature before starting the work.

5.4. Limitations of procedure

5.4.1. Certain drugs are known to cause positive reactions in anti-human globulin procedures.

5.4.2. Some pathological conditions are also reported as causing positive reactions in anti-human globulin procedures.

5.4.3. Bacterial or other contamination of materials used can cause false positive or false negative results.



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5.4.4. Fibrin residues in the red cell suspension may trap non-agglutinated cells presenting a fine pink line on top of the gel while most of the cells are on the bottom of the microtube after centrifugation.

6. Responsibility:

6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately.

6.2 It is the responsibility of assigned physician assigned in the area to assure implementation of policies and procedure.

7. References:

7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.

7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.

7.3. Leaflet from DiaMed for ID Liss Coombs Cards and ID Anti D.

7.4. Pictures provided by DiaMed for accurate pipetting procedure and grading the reaction.

7.5. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.6. CBAHI national standards for hospitals 3rd edition, 2015.



TITLE Direct Antiglobulin Test (DAT) By Gel Card.

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APPLIES TO: Transfusion Service Laboratory staff.

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> Immediate Spin Cross Match Technique. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-21 -V1 | <u>NUMBER OF PAGES:</u> 6 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform immediate spin cross match for patients requiring red cells transfusion whose antibody screen is negative.

2. Definitions:

2.1. Immediate Spin Cross Match Testing of patient serum against the blood donor's red cells by immediate spin to confirm ABO compatibility.

3. Equipment/Material/Forms:

- 3.1.** EDTA Blood Specimen.
- 3.2.** Selected blood unit/units.
- 3.3.** 12 x 75 test tubes.
- 3.4.** Normal saline.
- 3.5.** Transfer pipettes.
- 3.6.** Segment opener/ scissors.
- 3.7.** Bench top Centrifuge.
- 3.8.** Serological Centrifuge.
- 3.9.** Cotton gauze pads.
- 3.10.** Registration log book.
- 3.11.** Blood transfusion requests.



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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

4. Policy Statement:

- 4.1. It is the policy of transfusion service laboratory that blood can be issued by immediate spin cross match if the antibody screen of the patient by 3 cell panel is negative and patient has no previous history of un expected antibodies.
- 4.2. It is a policy of transfusion service lab NOT TO ISSUE blood component type specific for any patient unless that patient's blood group has been done TWO TIMES on two different samples, otherwise issue O PRBCs or AB FFP/ AB Platelets in emergency.
- 4.3. Transfusion request and sample receiving SOP shall be strictly followed.

5. Procedure

5.1. Principal Antigen Antibody Reaction is a reaction that occurs when an antibody combines with a corresponding antigen to produce an immune complex causing agglutination of red cells.

5.2. Procedure Steps:

- 5.2.1. Check all blood specimen and their identity (Patient's and patient's number).
- 5.2.2. Centrifuge the specimen for 5 minutes at 3000 rpm.
- 5.2.3. Bring selected units.
- 5.2.4. Record unit's numbers on your work sheet.
- 5.2.5. Label the tube/s to get blood from blood unit segment/s.



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5.2.6. Cut the segment and keep in the labeled tubes.

5.2.7. Cut the segments with a segment opener or a clean scissor (each unit clean scissor) and drop few drops of PRBC/WB from the segment.

5.2.8. Fill the tube 2/3 with normal saline and wash the cells 1 time.

5.2.9. Label 1 tube for each unit for preparation of donor cell suspension (3-5%).

5.2.10. Pipette one drop of this 3-5% cell suspension.

5.2.11. Add 2 drops of patient's plasma and mix.

5.2.12. Centrifuge the specimen for optimal time (pasted on machine).

5.2.13. Read the tube macroscopically.

5.3. Interpretation:

5.3.1. No agglutination or hemolysis means unit is ABO compatible.

5.3.2. Agglutination or hemolysis means.

- Unit is ABO incompatible (recheck blood group again).
- Unit red cells are polyagglutinable (wash with warm saline 3 times).
- Anti-A1 is in the serum of an A2 or A2B individual (cross match with group O).
- Cold antibody (do full cross match).

5.3.3. Write the result on your work sheet.



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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

6. **Responsibility:**

- 6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately.
- 6.2 It is the responsibility of blood bank physician assigned in the cross-match area to assure implementation of policy and procedure.

7. **References:**

- 7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.
- 7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.
- 7.3. Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.
- 7.4. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.5. CBAHI national standards for hospitals 3rd edition, 2015.



TITLE Immediate Spin Cross Match Technique.

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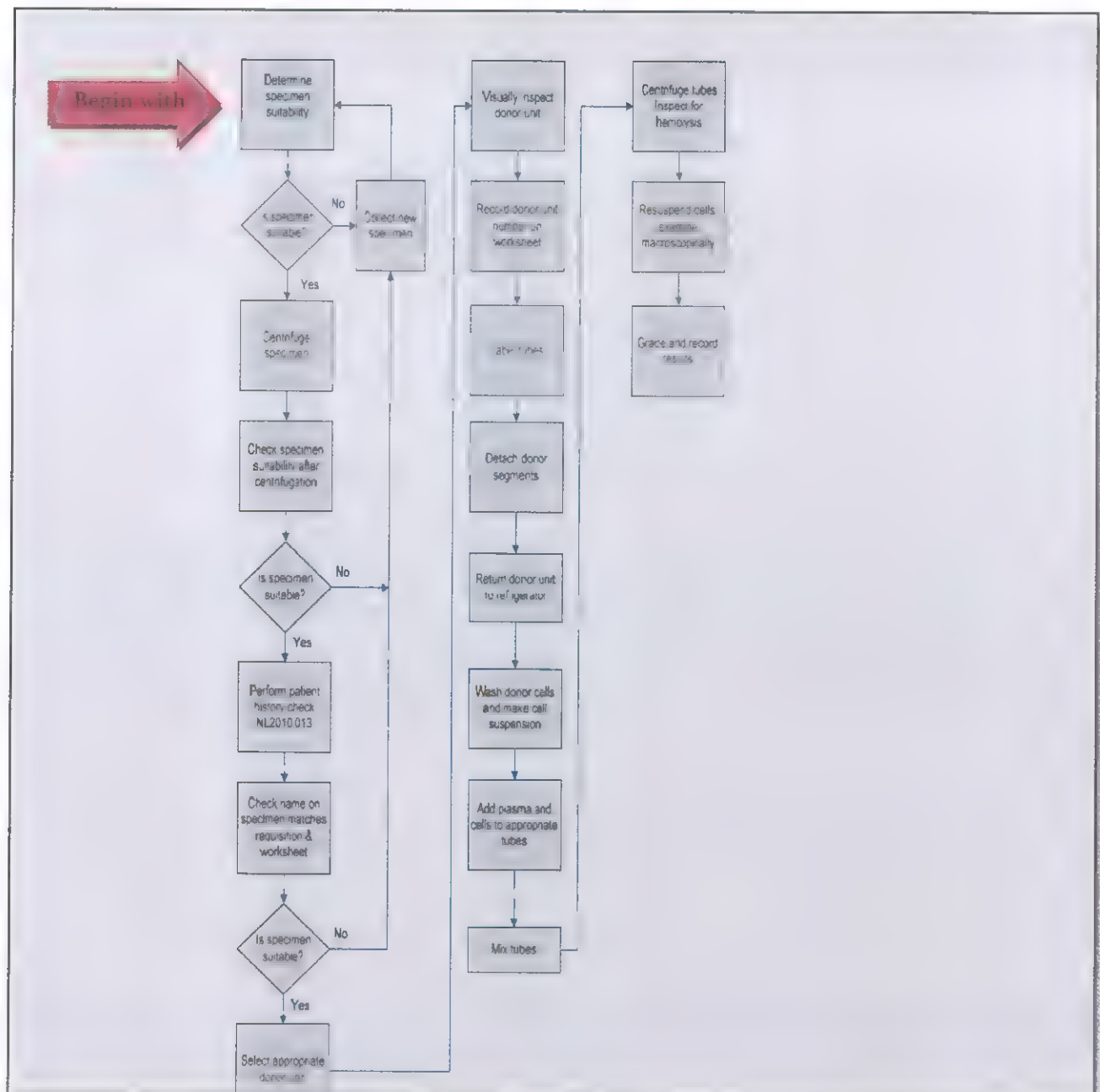
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Flow chart of Immediate Spin Cross Match Technique Procedure.





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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|--------------|------------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari ; | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> Compatibility testing -Cross Match Test By Tube Method Technique. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform cross match test for patients requiring red cells transfusion by tube method in correct way.

2. Definitions:

2.1 Cross Match (Complete /Anti Human Globulin) Testing of patient serum against the blood donors red cells up to Anti human Globulin phase (Coombs) to detect clinically significant anti bodies in patient serum those may cause a hemolytic transfusion reaction.

3. Equipment/Material/Forms:

- 3.1. EDTA Blood Specimen.
- 3.2. Selected blood unit/units.
- 3.3. Test tubes 10 x75.
- 3.4. Bovine Albumin 22%.
- 3.5. Transfer Pipette.
- 3.6. Segment opener/ scissors.
- 3.7. Serologic Centrifuge.
- 3.8. Bench Top Centrifuge.
- 3.9. Water Bath 37°C.
- 3.10. Antihuman Globulin reagent.
- 3.11. Coombs check cells.
- 3.12. Registration log book.
- 3.13. Blood transfusion requests.



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4. Policy Statement:

4.1.It is the policy of transfusion service lab to establish a process for compatibility testing which cover the following :

- a. There is a process to ensure the detection of ABO incompatibility between the recipient's serum/plasma and the donor's RBC.
- b. The process ensures the compatibility testing is performed on integrally attached segment from the donor's RBC unit.
- c. The process ensures the checking for presence, now or in the past, of clinically significant antibody in the patient's serum.
- d. The process ensures the proper labeling of cross-matched units with patient's name, patient's identification number and patient's ABO /Rh-D.

4.2.It is the policy of transfusion service lab to perform complete cross match up to Anti Human Globulin for all patients having unexpected antibody/antibodies or history of un expected antibody/antibodies.

4.3.It is a policy of transfusion service lab NOT TO ISSUE blood component type specific for any patient unless that patient's blood group has been done TWO TIMES on two different samples, otherwise issue O PRBCs or AB FFP/ AB Platelets in emergency.

4.4.Transfusion request and sample receiving SOP shall be strictly followed.



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5. Procedure

5.1. Principal

5.1.1. Antigen Antibody Reaction A reaction that occurs when an antibody combines with a corresponding antigen to produce an immune complex causing agglutination of red cells.

5.2. Procedure Steps

- 5.2.1.** Check all Blood specimen and their identity (Patient's and patient's number).
- 5.2.2.** Centrifuge the specimen for 5 minutes at 3000 rpm.
- 5.2.3.** Bring selected units.
- 5.2.4.** Label 1 tube for each unit for preparation of donor cell suspension (3-5%).
- 5.2.5.** Label another tube for each unit for cross-match.
- 5.2.6.** Cut the segment and keep in the labeled tubes accordingly.
- 5.2.7.** Cut the segments with a segment opener or a clean scissor (each unit clean scissor) OR and drop few drops of PRBC/WB from the segment.
- 5.2.8.** Wash the cells one time and prepare 3-5% Cell suspension.
- 5.2.9.** Pipette 1 drop cell suspension in the corresponding cross match tube.
- 5.2.10.** Pipette 2 drops of patient plasma to the respective tube/s.
- 5.2.11.** Centrifuge the tubes, read and record result of immediate spin.



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5.2.12. Add 2 drop of 22 % Albumin to each tube.

5.2.13. Mix and incubate in water bath for 15-30 minutes.

5.2.14. Mix, centrifuge at optimal speed, read and record the result of 37°
C phase.

5.2.15. Wash the cells by normal saline 3 times; decant the saline completely after 3rd wash.

5.2.16. Add 2 drops of mono-specific AHG IgG.

5.2.17. Mix, centrifuge at optimal speed, read and record the result of
AHG phase.

5.2.18. Add Coombs check cells to all negative tubes; the control cells must give positive result, if control cells are negative repeat the procedure carefully.

5.3. Interpretation of Reaction:

5.3.1. Positive result is presence of agglutination or Hemolysis which indicates incompatibility between donor and patient hence units cannot be issued.

5.3.2. Negative result is absence of agglutination or Hemolysis, indicates compatibility between donor and patient hence units can be issued to patient.

6. Responsibility:

6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service laboratory room to perform the procedure accurately.



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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

6.2 It is the responsibility of assigned physician to assure implementation of policies and procedure.

7. References:

- 7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.
- 7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.
- 7.3. Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.
- 7.4. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.5. CBAHI national standards for hospitals 3rd edition, 2015.



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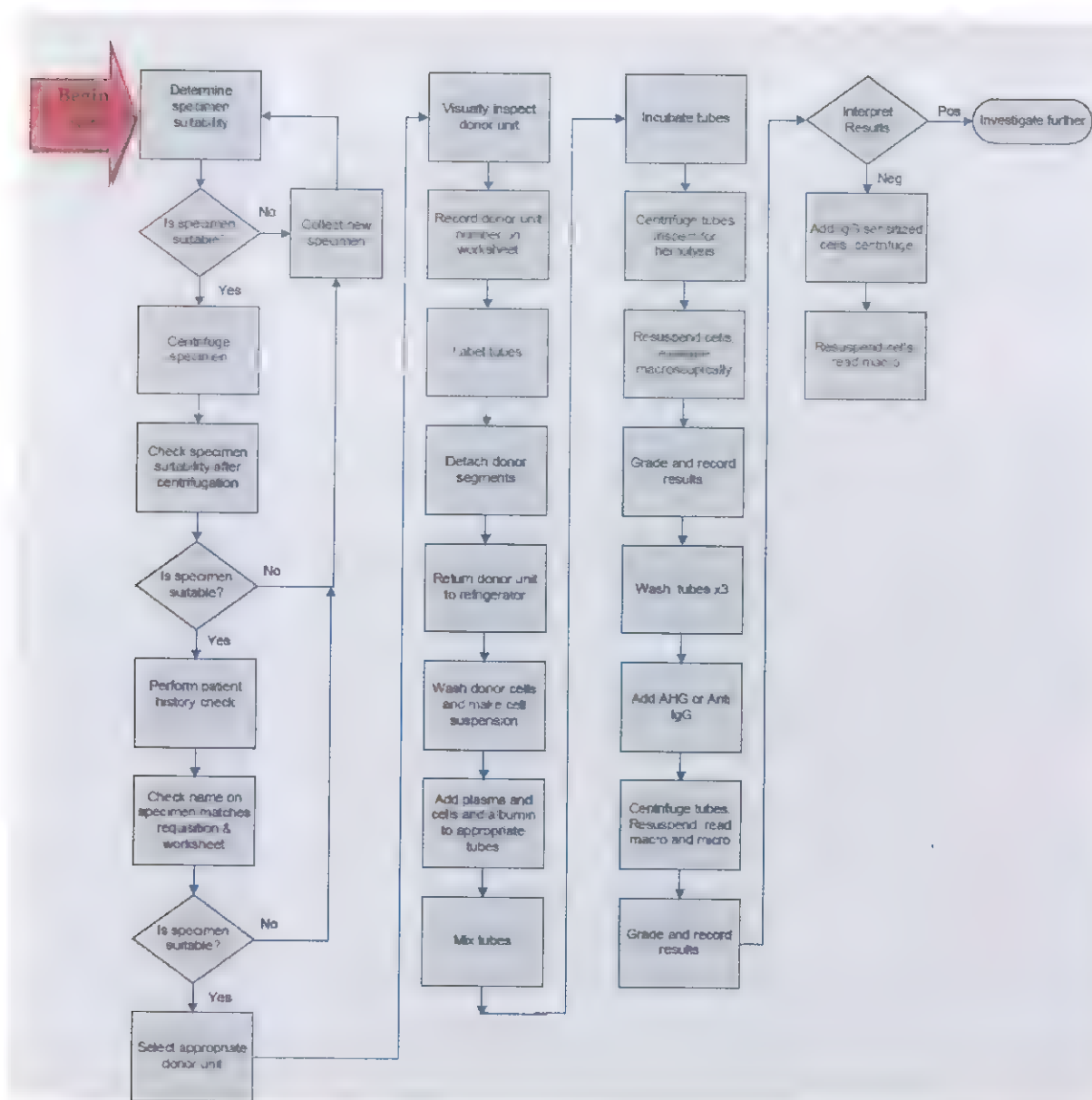
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Flow chart of cross-matching procedure:





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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|-----------|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab | | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab | | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair | | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab | | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. | | 1-5-2018 |



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| <u>TITLE</u> Compatibility testing -Cross Match Test By ID Gel Card Technique. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform cross match for patients requiring red cells transfusion by ID Gel Card in a correct way.

2. Definitions

2.1. Cross Match (Complete /Anti Human Globulin) Testing of patient serum against the blood donors red cells up to Anti human Globulin phase (Coombs) to detect clinically significant anti bodies in patient serum those may cause a hemolytic transfusion reaction.

3. Equipment/Material/Forms:

- 3.1. EDTA Blood Specimen.
- 3.2. Selected blood unit/units.
- 3.3. ID- Liss Coombs Cards.
- 3.4. ID-Diluent 2: modified LISS for red cell suspensions.
- 3.5. ID-Dispenser.
- 3.6. ID-Pipetor.
- 3.7. ID-Tips (pipetor tips).
- 3.8. Test Tubes.
- 3.9. Segment opener/ scissors.
- 3.10. ID-Working table.
- 3.11. ID-Centrifuge.



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3.12. Registration log book.

3.13. Blood transfusion requests.

4. Policy Statement:

4.1.It is the policy of transfusion service lab to establish a process for compatibility testing which cover the following :

- There is a process to ensure the detection of ABO incompatibility between the recipient's serum/plasma and the donor's RBC.
- The process ensures the compatibility testing is performed on integrally attached segment from the donor's RBC unit.
- The process ensures the checking for presence, now or in the past, of clinically significant antibody in the patient's serum.
- The process ensures the proper labeling of cross-matched units with patient's name, patient's identification number and patient's ABO /Rh-D.

4.2.It is the policy of transfusion service lab to perform complete cross match up to Anti Human Globulin for all patients having un expected antibody/antibodies or history of un expected antibody/antibodies

4.3.It is a policy of transfusion service lab NOT TO ISSUE blood component type specific for any patient unless that patient's blood group has been done TWO TIMES on two different samples, otherwise issue O PRBCs or AB FFP/ AB Platelets in emergency.

4.4.Transfusion request and sample receiving SOP shall be strictly followed.



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5. Procedure

5.1 Principal refer to ABO and Rh Grouping by gel card procedure.

5.2 Procedure Steps

5.2.1 Allow the test cell reagents and samples to reach room temperature before use.

5.2.2 Check all blood specimens and their identity (Patient's names and patient's number).

5.2.3 Centrifuge the specimen for 5 minutes at 3000 rpm.

5.2.4 Bring selected units.

5.2.5 Record unit's numbers on your work sheet.

5.2.6 Label the tube/s to get blood from blood unit segment/s.

5.2.7 Cut the segment and keep in the labeled tubes.

5.2.8 Cut the segments with a segment opener or a clean scissors (each unit clean scissor) and drop few drops of PRBC/WB from the segment.

5.2.9 Label 1 tube for each unit for preparation of donor cell suspension (0.8%).

5.2.10 Add 1 ml Diluent 2 to each tube.

5.2.11 Add 12.5 ul of PRBC or 25 ul of whole blood to the above labeled tubes.

5.2.12 Label ID Liss Coombs cards 1 microtubes for one unit.

5.2.13 Hold the card up right and remove the aluminum foil.

5.2.14 Pipette the cell suspension and plasma as shown in picture below.



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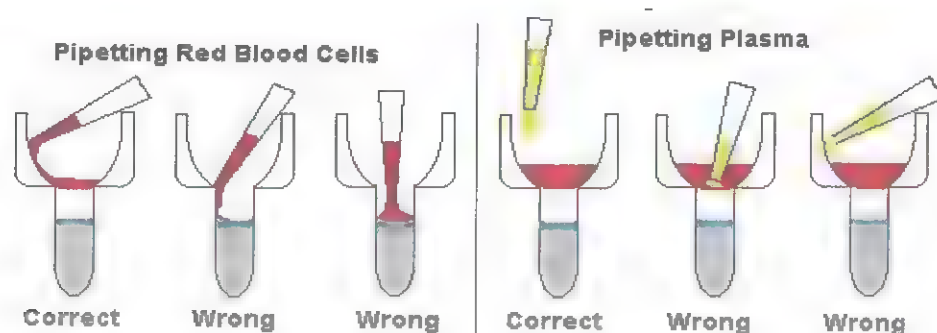
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APPLIES TO: Transfusion Service Laboratory staff.



5.2.15 Pipette 50ul of donor cell suspension to respective labeled microtube.

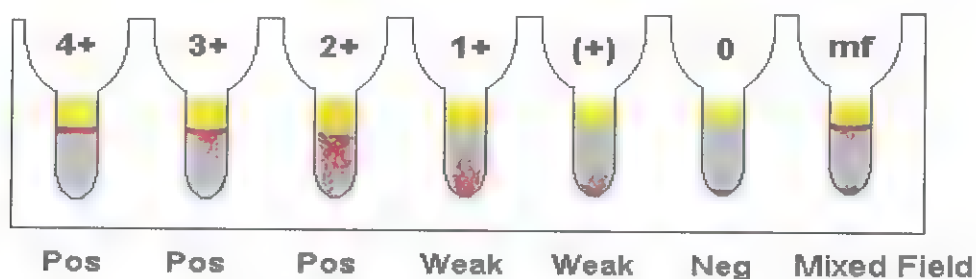
5.2.16 Pipette 25ul of patient's plasma to the respective tube/s.

5.2.17 Incubate the ID-Card for 15 minutes at 37 °C in the ID-Incubator.

5.2.18 After incubation Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.

5.2.19 Let centrifuge stop , take out the card, read and record the result.

5.3 Interpretation: Interpret agglutination as follows:



5.3.1 No agglutination (0) reaction is a compatible unit.

5.3.2 Write the result on your work sheet.



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5.3.3 If the test is positive, so the blood unit is incompatible, unsuitable for transfusion to that patient.

5.3.4 **Precautions and Limitations of procedure:** refer to ABO and Rh Grouping by gel card procedure.

6. Responsibility:

6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately.

6.2 It is the responsibility of assigned physician in the cross-match area to assure implantation of policies and procedure.

7. References

7.1 Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.

7.2 Leaflet from DiaMed for ID Liss Coombs Cards.

7.3 Pictures provided by DiaMed for accurate pipetting procedure and grading the reactions.

7.4 Technical Manual of American Association of Blood Banks, 18th edition 2014.

7.5 Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.

7.6 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|-----------|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab | | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab | | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair | | 15-4-2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab | | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. | | 1-5-2018 |



TITLE Compatibility Testing- Cross Matching Test By Pre Warm Procedure.

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APPLIES TO: Transfusion Service Laboratory staff.

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory s staff to perform cross matching test by pre warm procedure if patient has cold anti-bodies/agglutinin.

2. Definitions:

2.1 Cold Agglutinin: an unspecific antibody found on the surface of RBCs in certain diseases and may cause clumping of the RBC below 36 ° C and may cause hemolysis.

2.2 Auto agglutinations caused by cold antibody that is removed by warm saline washing and by pre-warm procedures.

3. Equipment/Materials:

3.1 EDTA Blood Specimen.

3.2 Normal Saline.

3.3 Water Bath.

3.4 Serofuge.

3.5 Test Tubes 12x75.

3.6 Disposable Transfer pipettes.

3.7 Bench Top Centrifuge.

3.8 AHG mono specific IgG.

3.9 Commercially available group O antibody detection red cells.

3.10 IgG-coated red cells.



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4. Policy Statement:

- 4.1 It is the policy of transfusion service lab to perform pre-warm cross match only if it is suspected that the patient has cold auto antibodies.
- 4.2 Prewarming may be useful in the detection and identification of red cell antibodies that bind to antigen only at 37⁰ C.
- 4.3 It is the policy of transfusion service lab to establish a process for compatibility testing which cover the following :
- a. There is a process to ensure the detection of ABO incompatibility between the recipient's serum/plasma and the donor's RBC.
 - b. The process ensures the compatibility testing is performed on integrally attached segment from the donor's RBC unit.
 - c. The process ensures the checking for presence, now or in the past, of clinically significant antibody in the patient's serum.
 - d. The process ensures the proper labeling of cross-matched units with patient's name, patient's identification number and patient's ABO /Rh-D.

5. Procedure :

5.1 Specimen: Serum or plasma may be used.

5.1.1 If possible bring the specimen in EDTA tube from ward in at 37^{0C}.

5.1.2 For Patient samples check all the entries on request and blood specimen, especially the identities must be same.



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5.1.3 Incubate the specimen at 37°C for 15-30 minutes as soon arrived to the lab.

5.1.4 Perform blood group.

5.2 Performing Antibody Screening ;

5.2.1 Centrifuge the specimen for 10 minutes at 3000 rpm.

5.2.2 Remove plasma and incubate at 37 ° C for 15-30 minutes.

5.2.3 Incubate Normal saline wash bottle for 15-20 minutes in water bath at 37 C.

5.2.4 Label one tube for each reagent cell to be tested. (3 cell panel for tube.

5.2.5 Add 1 drop of 2% to 5% saline-suspended red cells to each tube.

5.2.6 Place the tubes containing red cells and a tube containing a small volume of the patient's serum and a pipette at 37 ° C; incubate for 5 to 10 minutes.

5.2.7 Using the prewarmed pipette, transfer 2 drops of prewarmed serum to each tube containing prewarmed red cells. Mix without removing tubes from the incubator.

5.2.8 Incubate at 37 ° C for 30 to 60 minutes.

5.2.9 Without removing the tubes from the incubator, fill each tube with prewarmed (37 C) saline. Centrifuge and wash three or four times with 37 C saline.



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5.2.10 Add anti-IgG according to the manufacturer's directions.

5.2.11 Centrifuge and observe for reaction. Grade and record the results.

5.2.12 Confirm the validity of negative results by adding IgG-coated red cells.

5.3 Performing crossmatching with the patient and the PRBC :

5.3.1 Bring the blood PRBC units accordingly.

5.3.2 Incubate the patient sample for 15-20 minutes in water bath at 37⁰

5.3.3 Take the red cell from sample and wash them by warm normal saline.

5.3.4 Prepare 3-5% cell suspension from the units and incubate 37⁰ C for 15-30 minutes.

5.3.5 Label 12 x 75 mm tubes for cross match.

5.3.6 Add 1 drop of donor cell suspension and 2 drops of patient serum.

5.3.7 Mix and incubate at 37°C for 45-60 minutes.

5.3.8 Remove the tubes, centrifuge for optimal time and read for agglutination and hemolysis (37C reading).

5.3.9 Wash for 3 times by warmed saline.

5.3.10 Add 2 drops AHG mono specific IgG to each tube.



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5.3.11 Centrifuge for optimal time and read for agglutination and hemolysis. (AHG reading).

5.4 Interpretation:

5.4.1 There is No agglutination or hemolysis: Compatible cross match.

5.4.2 There is Agglutination or hemolysis: Incompatible cross match.

5.5 Precautions:

5.5.1 Activate this policy if it is sure that the patient has auto cold antibodies, try to look for underlying allo- anti bodies.

5.5.2 Do not add albumin or excessive amount of serum. Observe cells 1 drop: serum/plasma drops strictly.

5.5.3 Do not perform immediate spin.

5.5.4 The prewarming procedure will not detect alloantibodies that agglutinate at 37 C or lower and are not reactive in the antiglobulin phase. If detection of these antibodies is desired, testing and centrifugation of a duplicate tube at 37 C is required.

5.5.5 If time permits, a tube containing a prewarmed mixture of serum and cells can be incubated at 37 ° C for 60 to 120 minutes, and the settled red cells can be examined for



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agglutination by resuspending the button without centrifugation.

5.5.6 Cold-reactive antibodies may not be detectable when room temperature saline instead of 37 C saline is used in the wash step. The use of room temperature saline may avoid the elution of clinically significant antibody (ies) from reagent red cells that can occur with the use of 37 C saline.

5.5.7 Some strong cold-reactive autoantibodies, however, may still react and therefore require the use of 37⁰ C saline to avoid their detection.

6. Responsibility:

6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service laboratory room to perform the procedure accurately.

6.2 It is the responsibility of assigned physician to assure implementation of policies and procedure.

7. References:

7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.

7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.

7.3. Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.








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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

7.4. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.5. CBAHI national standards for hospitals 3rd edition, 2015.

8. Approvals:

| | Name | Title | Signature | Date |
|--------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 14-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service lab staff to perform anti body identification for patients by tube method in an accurate way.

2. Definitions:

2.1. Anti-Body Identification: Identification of un expected anti bodies by a known panel of red cells usually 11 cell panel and in case of multiple antibodies or cold antibodies enzyme treatment or specialized procedures like adsorption/elution etc.

2.2. Unexpected Antibodies: Anti-bodies against RBCs antigen produced by plasma cells in antigenic response other than the naturally occurring A and B antibodies

3. Equipment/Material/Forms:

3.1. EDTA Blood Specimen or eluate from an elution procedure.

3.2. Panel Cells and sheet.

3.3. LISS/Albumin 22%.

3.4. Anti Human Globulin.

3.5. Coombs Check Cells.

3.6. Test Tubes 12 x 75.

3.7. Water Bath.

3.8. Disposable Transfer Pipette (Pasteur).

3.9. Normal Saline/ Wash Bottle.



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3.10. Serological Centrifuge.

3.11. Bench Top Centrifuge.

4. Policy Statement:

4.1. It is the policy of transfusion service lab to identify unexpected/unnatural antibodies found in any patient who has positive antibody screening to supply the patient with corresponding antigen negative blood.

4.2.If The Transfusion Service Laboratory Have Not Reagents For Antibody Identification: policy and procedures of requesting blood products from other MOH health facility should applied.

5. Procedure

5.1. Procedure Steps

- 5.1.1.** Allow the test cell reagents and samples to reach room temperature before use.
- 5.1.2.** Check all blood specimens and their identity (Patient's names and patient's number).
- 5.1.3.** Centrifuge the specimen for 5 minutes at 3000 rpm.
- 5.1.4.** Label 12 tubes cell 1, cell 2 and so on cell 11, 12th tube AC for auto control and sample number on all 12 tubes.
- 5.1.5.** Prepare 3-5% patient cell suspension.



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5.1.6. Pipette reagent cells 1 drop to tube one and reagent cell 2 to tube 2 and so on cell 11 to tube 11 and patient cell to tube 12 labeled as AC.

5.1.7. Pipette 2 drops of patient serum/Plasma to all 12 tubes.

5.1.8. Mix, centrifuge for optimal time labeled on the machine.

5.1.9. Mix and read the reactions macroscopically for agglutination/hemolysis, record the results in sheet.

5.1.10. Add 2 drops of Bovine Albumin 22%, mix and incubate at 37°C for 15-30 minutes.

5.1.11. Mix, centrifuge for 30 seconds and record the result note in the sheet any hemolysis or agglutination.

5.1.12. Wash the cells 3 time, decant all saline and add 2-3 drops of Antihuman globulin serum, mix and centrifuge.

5.1.13. Read and record on the panel sheet.

5.1.14. Add 1 drops of coombs check cell to all negative reaction tubes.

5.1.15. Mix, centrifuge and read the results. All negative reactions must be positive. In case of a negative reaction, repeat all procedure from beginning. Look errors in cell washing or additions of coombs serum.



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5.2. Interpretation of Reaction:

- 5.2.1. Positive result is agglutination or hemolysis which indicates the presence of antibodies.
- 5.2.2. Negative result is absence of agglutination or hemolysis, which indicate absence of antibodies.
- 5.2.3. Interpret agglutination as follows:

5.3. Interpretation of Anti body

- 5.3.1. If the pattern of positive and negative reaction observed, antibodies can be eliminated to the antigens present on the non-reactive cells using the panel sheet and considering one cell at a time, eliminate all of the antigen that are represented homozygous on the cells give negative reaction. Cross out the antigens at the top of the table in panel sheet.
- 5.3.2. If the pattern of positive reaction shows the same strength, this is mostly means single antibody and reaction of different strengths mostly means multiple antibodies.
- 5.3.3. If only one antigen is remaining observe the overall pattern of positive and negative cells to see if the serum reaction matches that of the positive cells of that antigen
- 5.3.4. Patient should be negative for the antigen corresponds to identified antibody, unless the patient has been transfused in last 3 months,



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5.3.5. Reaction phase:

- I.S. phase reactivity indicates the presence of cold/ room temperature reacting antibodies (IgM), such as, anti- lewis, I,i, P1and MN.
- Reactivity at 37 C phase and AHG phase indicates presence of warm (IgG), such as anti-Rh, kell, kidd, and duffy etc.

5.3.6. Autocontrol:

- If the serum and autocontrol both are reactive, suggestive of autoantibodies, but cannot ruled out the presence of allo antibodies.
- If autocontrol is positive in AHG phase, perform DAT by Coombs IgG and if positive, prepare eluate and test elute for antibody identification.

5.3.7. Dosages:

- Duffy, Kidd, Rh and MNS show dosage effect.
- Antibody to high frequency antigen suggested by reactivity to all panel cells except autocontrol with same strength of reactivity.

5.3.8. Panagglutination :

- Equal strength Reactivity with all cells including autocontrol indicates nonspecific panagglutination.



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- b. Wash panel cells to rule out alloantibodies or reactivity to preservative solution.

5.3.9. Extended Work Up:

- a. Perform a selected cell panel by choosing additional cells to include cells both positive (homozygous) and negative for each of those antigens not excluded.
- b. Consider the possibility of antibodies to additional antigens other than the obvious ones that are not ruled out in its presence. For example, if the reactions correspond to an anti-c and all E positive cells are also c positive, the presence of anti-E cannot be ruled out. Select cells from other red cell panels that are c negative and E positive and repeat the tests. Anti-c frequently occurs with anti-E and anti-e with anti-C.
- c. Similarly, an anti-c may conceal the presence of an anti-K or other antibody.
- d. Select cells negative for c antigen and positive for the questionable antigen.
- e. If the observed pattern does not fit any specific pattern, there may be a combination of antibodies present. Perform the following steps to identify and rule out antibodies.
- f. Antigen type the patient for antigens corresponding to all antibodies not ruled out if he/she is not transfused within last



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three months. A patient will not produce allo-antibodies toward an antigen present on their own red cells. Therefore, if the patient's red cells type positive for the antigen, they cannot develop the corresponding antibody and it can be ruled out as an alloantibody.

- g. If it appears that Anti-Fya or anti-Fyb is present, run an enzyme panel to detect antibodies that are masked by the anti-Fya or anti-Fyb.
- h. If anti-P1 or anti-Lea or anti-Leb is present, or if anti-Sda is suspected, neutralization (Neutralization with Group Specific Substances) will frequently confirm an antibody or remove one or more antibodies allowing the identification of others.
- i. (Acid Elution) can be used to separate specific antibodies.
- j. If a specific antibody pattern isn't demonstrated, it may be due to weak reactivity of the antibody. Weak reactions may be enhanced in several ways:
- k. Perform elution to separate specific antibodies.

5.3.10. Weak reaction can be enhanced by:

- a. Increase incubation time.
- b. Increase serum to cell ratio.
- c. Test serum against enzyme panel.



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5.3.11. Perform pre warm panel or autologous adsorption to avoid antibodies react at room temperature (clinically non significant antibodies) which can mask the presence of clinically significant antibodies.

5.3.12. If I.S. reactivity due to anti-P, anti-I, anti-M, and anti-N:Disappeared at 37°C phase AHG phase, indicates that these antibodies are clinically non significant.If still persist at 37°C phase AHG phase – so it is clinically significant.

5.3.13. Previously Identified Antibodies:

- a. Select panel that is negative for previously reactive antibody, but positive to all other clinically significant antigens.
- b. Perform autocontrol.
- c. Previously identified antibody needs not to re-identify (But the patient has to be transfused with units negative to this Ag).

5.3.14. Reporting Results:

- a. Complete immunohematology report form with the type of identified antibody, together with all screening cell antigrams panel sheet and antigen typing form.
- b. For the patient with previously identify antibody, report the result as no additional antibody detected, if the panel of selected cells found negative.



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5.3.15. Procedure Notes:

- a. Grade the reactions and record on panel sheet.
- b. Use 2 heterozygous cells, if homozygous cells are not available, to perform exclusion.
- c. Clinically significant antibodies are those antibodies, which can lead to shortened survival of transfused red cells or causes hemolytic disease of newborn (HDN), such as, Rh system, kell, kidd, duffy, Ss & U, Diago, Dombroch, Gerbich, Cromer etc.
- d. If new sample is required, perform ABO/Rh grouping and repeat with one more positive cells that has the same result.
- e. If a new antibody is detected in obstetrics patient, perform antibody titration and report them without waiting for titration order.
- f. Frequency of antibody testing: for a patient who has been pregnant or received red cells within preceding 3 months, antibody detection and compatibility tests must be done on a specimen obtained within 3 days of the next scheduled transfusion.
- g. Consider testing a fresher sample when there have been repeated transfusions within the 3 days period, especially if clinical evidence suggests failure of transfused red cells to survive as expected.



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6. Responsibility:

6.1 It is the responsibility of staff (assigned technician or technologist) in Transfusion Service Laboratory to perform the procedure accurately.

6.2 It is the responsibility of assigned physician to assure implantation of policies and procedure.

7. References:

7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.

7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.

7.3. Leaflet from DiaMed Panel Cell.

7.4. Leaflet from DiaMed Coombs Control Check Cells.

7.5. Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.






7.6. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.7. CBAHI national standards for hospitals 3rd edition, 2015.



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8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform anti body identification for patients by ID gel card in an accurate way.

2. Definitions:

2.1. Unexpected Antibodies: Anti-bodies against RBCs antigen produced by plasma cells in antigenic response other than the naturally occurring A and B antibodies.

2.2. Anti-Body Identification: Identification of un expected anti bodies by a known panel of red cells usually 11 cell panel and in case of multiple antibodies or cold antibodies enzyme treatment or specialized procedures like adsorption/elution etc.

3. Equipment/Material/Forms:

3.1. EDTA blood Specimen or elute from an elution procedure.

3.2. ID- Liss Coombs Cards.

3.3. ID-DiaCells Panel and panel sheet.

3.4. ID-Diluent 2: modified LISS for red cell suspensions.

3.5. ID-Dispenser.

3.6. ID-Pipetor.

3.7. ID-Tips (pipetor tips).

3.8. Suspension Tubes.

3.9. ID-Working table.



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3.10. ID-Centrifuge.

4. Policy Statement:

4.1. It is the policy of transfusion service lab to identify unexpected/unnatural antibodies found in any patient who has positive antibody screen to supply the patient with antigen negative blood to his detected antibody, if needed.

4.2.If The Transfusion Service Laboratory Have Not Reagents For Antibody Identification: policy and procedures of requesting blood products from other MOH health facility should applied.

5. Procedure

5.1. Procedure Steps

5.1.1. Allow the test cell reagents and samples to reach room temperature before use.

5.1.2. Check all blood specimens and their identity (Patients name and number).

5.1.3. Centrifuge the specimen for 5 minutes at 3000 rpm.

5.1.4. Prepare 0.8% patient cell suspension.

5.1.5. Label ID Liss Coombs cards 12 microtubes for one patient Cell 1, 2, up to 11 and AC number 12 with patient lab number.

5.1.6. Hold the card up right and remove the aluminum foil.

5.1.7. Pipette the cell suspension and plasma as shown in picture below.

5.1.8. Pipette 50ul of ID DiaCell 1 to micro tube 1, ID Diacell 2 to microtube number 2 and so on cell 11 to tube 11.



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5.1.9. Pipettes 50 ul of patient cell suspension to microtube 12 labeled as AC.

5.1.10. Pipette 25ul of plasma to the 12 microtubes for that patient.

5.1.11. Incubate the ID-Card for 15 minutes at 37°C in the ID-Incubator.

5.1.12. After incubation Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.

5.1.13. Let centrifuge stop, take out the card and read.

5.1.14. Record the result on panel sheet including

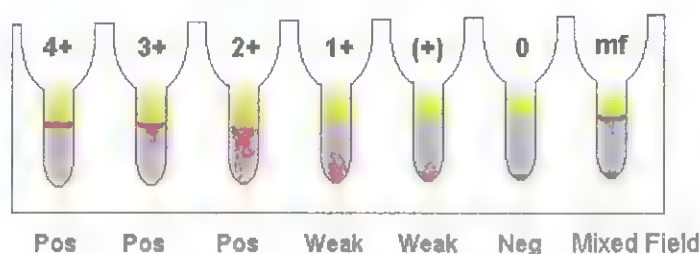
- Patient's three names.
- Patient's number.
- Date

5.2. Interpretation of Reaction:

5.2.1. Positive result is agglutination or Hemolysis which indicates the presence of antibodies.

5.2.2. Negative result is absence of agglutination or Hemolysis, which indicate absence of antibodies.

5.2.3. Interpret agglutination as follows





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5.3. Interpretation of Anti body

- 5.3.1. If the pattern of positive and negative reaction observed, antibodies can be eliminated to the antigens present on the non-reactive cells using the panel sheet and considering one cell at a time, eliminate all of the antigen that are represented homozygous on the cells give negative reaction. Cross out the antigens at the top of the table in panel sheet.
- 5.3.2. If the pattern of positive reaction shows the same strength, this is mostly means single antibody and reaction of different strengths mostly means multiple antibodies.
- 5.3.3. If only one antigen is remaining observe the overall pattern of positive and negative cells to see if the serum reaction matches that of the positive cells of that antigen.
- 5.3.4. Patient should be negative for the antigen corresponds to identified antibody (through the antigen phenotype), unless the patient has been transfused in last 3 months.
- 5.3.5. Auto control:
- If the patient sample and auto control both reveals reactive, suggestive of autoantibodies, but cannot be rule out the presence of allo antibodies.
 - If auto control is positive, perform DAT and if DAT positive by Coombs IgG perform elution and test elute for antibody.



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5.3.6. Dosages:

- a. Duffy, Kidd, Rh and MNS show dosage effect.

5.3.7. Antibody to high frequency antigen suggested by reactivity to all panel cells except autocontrol with same strength of reactivity.

5.3.8. Panagglutination :

- a. Equal strength Reactivity with all cells including auto control indicates nonspecific pan agglutination.
- b. Wash panel cells to rule out alloantibodies or reactivity to preservative solution.

5.3.9. Extended Work Up:

- a. Perform a **selected cell panel** by choosing additional cells to include cells both positive (homozygous) and negative for each of those antigens not excluded.

5.3.9.a.1. Consider the possibility of antibodies to additional antigens other than the obvious ones that are not ruled out in its presence. For example, if the reactions correspond to an anti-c and all E positive cells are also c positive, the presence of anti-E cannot be ruled out. Select cells from other red cell panels that are c negative and E positive and repeat the tests. Anti-c frequently occurs with anti-E and anti-e with anti-C.



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5.3.9.a.2. Similarly, an anti-c may conceal the presence of an anti-K or other antibody.

5.3.9.a.3. Select cells negative for c antigen and positive for the questionable antigen.

- b.** If the observed pattern does not fit any specific pattern, there may be a **combination of antibodies** present. Perform the following steps to identify and rule out antibodies.
 - a.** Antigen type the patient for antigens corresponding to all antibodies not ruled out if he/she is not transfused red cells within last three months. A patient will not produce allo-antibodies toward an antigen present on their own red cells. Therefore, if the patient's red cells type positive for the antigen, they cannot develop the corresponding antibody and it can be ruled out as an alloantibody.
 - b.** If it appears that Anti-Fya or anti-Fyb is present, run an enzyme panel to detect antibodies that are masked by the anti-Fya or anti-Fyb.
 - c.** If anti-P1 or anti-Lea or anti-Leb is present, or if anti-Sda is suspected, neutralization (Neutralization with Group Specific Substances) will frequently confirm



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an antibody or remove one or more antibodies allowing the identification of others.

- d. (Acid Elution) can be used to separate specific antibodies.
- c. If a specific antibody pattern isn't demonstrated, it may be due to **weak reactivity** of the antibody. Weak reactions may be enhanced in several ways:
 - 5.3.9.c.1. Increase the incubation time. (Do not incubate LISS additive longer than 30 minutes).
 - 5.3.9.c.2. Increase the ratio of serum to cells e.g., 4 or 5 drops of serum to 1 drop of cells. (DO NOT use LISS Additive).
 - 5.3.9.c.3. An antibody which reacts best at room temperature and decreases in reactivity as the temperature increases is usually considered to be **non-clinically significant**. These antibodies may mask the presence of a clinically significant warm antibody. Perform a pre-warmed panel or autologous adsorption) to help detect and identify other antibodies.
 - 5.3.9.c.4. If anti- M, N, or P is identified that reacts at the AHG phase, perform prewarm testing.
 - 5.3.9.c.5. If the reactivity is eliminated upon pre-warming, report the antibody as **non-clinically significant**.



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5.3.9.c.6. If it is positive in AHG phase after prewarming, report the antibody as being **clinically significant**.

5.3.10. Previously Identified Antibodies:

- Select panel that is negative for previously reactive antibody, but positive to all other clinically significant antigens.
- Perform auto-control.
- Previously identified antibody needs not to re-identify (But the patient has to be transfused with units negative to this Ag).
- For the patient with previously identify antibody, report the result as no additional antibody detected, if the panel of selected cells found negative.

5.3.11. Procedure Notes:

- Use 2 heterozygous cells, if homozygous cells are not available, to perform exclusion.
- Clinically significant antibodies are those antibodies, which can lead to shortened survival of transfused red cells or causes hemolytic disease of newborn (HDN), such as, Rh system, kell, kidd, duffy, Ss & U, Diago, Dombroch, Gerbich, Cromer etc.
- If new sample is required, perform ABO/Rh grouping and repeat with one more positive cells that has the same result.



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- d. If a new antibody is detected in obstetrics patient, perform antibody titration and report them without waiting for titration order.
- e. Frequency of antibody testing: for a patient who has been pregnant or received red cells within preceding 3 months, antibody detection and compatibility tests must be done on a specimen obtained within 3 days of the next scheduled transfusion.
- f. Consider testing a fresher sample when there have been repeated transfusions within the 3 days period, especially if clinical evidence suggests failure of transfused red cells to survive as expected.

6. Responsibility:

- 6.1 It is the responsibility of staff (assigned technologist) in Transfusion Service Laboratory to perform the procedure accurately.
- 6.2 It is the responsibility of assigned physician to assure implementation of policy and procedure.

7. References:

- 7.1 Technical Manual of American Association of Blood Banks, 18th edition 2014.
- 7.2 Leaflet from DiaMed for ID Liss Coombs Cards and ID DiaCell Panel.



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7.3 Pictures provided by DiaMed for accurate pipetting procedure and grading the reactions.

7.4 Standards for Blood Bank and Transfusion Services .Bethesda, MD:
American Association of Blood Bank 30th edition, 2016.






7.5 The unified Practical Manual for Blood Banks in Arab Countries
(MOH) 2013.

7.6 CBAHI national standards for hospitals 3rd edition, 2015.



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8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform gentle heat elution to study antibodies coated patient red cells causing DAT/AC positive.

2. Definitions:

2.1. Gentle Heat Elution is a procedure by which bounded antibodies are removed from red cells for the study of red cells, red cell are not hemolyzed but are available free of antibodies for phenotyping.

3. Equipment/Material/Forms:

3.1. EDTA, DAT Positive Blood Specimen.

3.2. Normal saline (0.9 % NaCl).

3.3. 6% bovine albumin.

3.4. Test tubes (12 mm x 75 mm).

3.5. Table top centrifuge.

3.6. Cell washer.

3.7. Water bath (45°C).

3.8. Marker pen/pencil.

3.9. Transfer pipettes.

4. Policy Statement:

4.1. It is the policy of transfusion service lab to perform gentle heat elution test if a patient DAT/AC is positive and it needs to be investigated.



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5. Procedure:

5.1. Principal

5.1.1. If patient's DAT/AC is positive, the gentle heat elution is best suited.

- a. For the determination of weak Rh (D).
- b. Phenotype requiring AHG phase.

5.2. Procedure Steps :

5.2.1. Place 1 volume of washed, antibody coated red cells and 3 volumes of normal saline in 1st test tube of appropriate size.

5.2.2. In 2nd test tube, place same volume of saline and washed red cells positive for antigen under test. This will provide a check that the elution technique does not destroy the antigen reactivity.

5.2.3. Incubate both tubes at approximately 45°C for 10-15 minutes. The tube should be agitated frequently. The time of incubation should be roughly proportional to the degree of an antibody coating, as indicated by strength of AHG reactivity.

5.2.4. Centrifuge the tubes and discard the supernatant saline.

5.2.5. Test the patient's cells for degree of antibody removal by comparing DAT on treated cells with the DAT results on untreated red cells. If the antibody coating is reduced but still present, repeat step 1-4. The control cells should be subjected to similar second treatment.



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5.2.6. Test the treated cells for the desired antigen.

5.3. Procedure Note:

5.3.1. This procedure become unnecessary if IgM monoclonal reagents are available. These reagents cause direct agglutination and are not affected by bound immunoglobulin.

5.3.2. As with non-treated patient's cells, results of antigen typing in recently transfused patients should be interpreted with caution because of the potential presence of donor cells.

6. Responsibility:

6.1. It is the responsibility of staff (assigned technician or technologist) in transfusion service lab to perform the procedure.

6.2. It is the responsibility of assigned physician to assure implementation of policies and procedure.

7. References:






7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.

7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.



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8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> Red Cell Antigen Pheno-Typing. | | | |
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1. **Statement Of Purpose:**

The purpose of this policy is to provide guidance to transfusion service laboratory staff to perform red cell antigen pheno-typing smoothly and in an accurate way.

2. **Definitions:**

2.1. Phenotype: Phenotypes result from the expression of an organism's genes as well as the influence of environmental factors and the interactions between the two. In terms of blood bank phenotyping is determination of blood group antigen by antigen antibody reaction.

2.2. Common Blood Group Antigens: A, B, D, C, E, c, e, K, k, Fy^a, Fy^b, Jk^a, Jk^b, Le^a, Le^b, P1, M, N, S,s, Lu^a.Lu^b

3. **Equipment/Material/Forms:**

- 3.1. EDTA Blood Specimen.
- 3.2. Anti-serum according to requirement.
- 3.3. Test Tubes 12 x 75.
- 3.4. Normal Saline in wash bottle.
- 3.5. Manual Cell Washer.
- 3.6. Bench Top Centrifuge.



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4. Policy Statement:

- 4.1. It is the policy of transfusion service lab to detect red cell antigen phenotype of the patients if he/she has an unexpected antibody and transfuse him relevant antigen negative blood after doing the phenotype of the blood units.
- 4.2. It is the policy of transfusion service lab to detect red cell antigen phenotype of the patients if he/she has an unexpected antibody if needed to confirm presence of that unexpected antibody.
- 4.3. It is the policy of transfusion service lab to perform extended antigen phenotype to newly diagnosed patient (blood dependent patient e.g. thalassemia) upon clinician request.

5. Procedure

5.1 Principal: A reaction that occurs when an antibody combines with a corresponding antigen to produce an immune complex causing agglutination of red cells (antigen antibody reaction).

5.2 Procedure Steps:

- 5.1.1. Bring required anti-serum according to panel results.
- 5.1.2. Allow the test cell reagents and samples to reach room temperature before use.
- 5.1.3. Check all blood specimen and their identity (patients three name and medical record number).



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5.1.4. Prepare 3-5% red cells suspension to be tested

5.1.5. Follow the leaflet provided by the manufacturer to proceed. Some anti-sera will require room temperature and some Coombs phase.

5.1.6. Record the results.

6. Responsibility:

6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately.

6.2 It is the responsibility of physician assigned in the area to assure implementation of policies and procedure.

7. References:

7.1 Technical Manual of American Association of Blood Banks, 18th edition 2014.





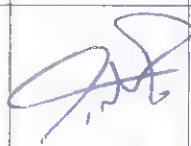
7.2 Leaflet from the manufacturer.

7.3 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.



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| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
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| <u>TITLE</u> Antibody Titration. | | | |
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1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service staff to perform antibody titration in an accurate way.

2. Definitions:

2.1. Anti-Body A protein substance secreted by plasma cells in response to and interacting specifically with an antigen.

2.2. Unexpected Antibodies: Anti bodies produced in antigenic response other than the naturally occurring A and B antibodies

2.3. Titration: Titration is a semi-quantitative method used to determine the concentration of antibodies in patient's blood sample.

2.4. Anti-Body Titer: The antibody titer is expressed as a reciprocal of the highest dilution of serum that causes agglutination of relevant antigen carrying cells.

3. Equipment/Material/Forms:

3.1. EDTA Blood Specimen.

3.2. Screening Cells having antigen for corresponding anti body or the cells by which IAT is positive.

3.3. Anti-Human Globulin IgG.

3.4. Coombs Check Cells.

3.5. Test Tubes 12 x 75.

3.6. Water Bath.

3.7. Disposable Transfer Pipette (Pasteur).

3.8. Normal Saline/ Wash Bottle.

3.9. Serological Centrifuge.

3.10. Bench Top Centrifuge.



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4. Policy Statement:

- 4.1. It is the policy of transfusion service staff to perform antibody titer for a positive IAT test by tube method only.
- 4.2. It is the policy of transfusion service staff to perform antibody titration especially for pregnant patients who have anti D.

5. Procedure

5.1. Principal

5.1.1. Antigen Antibody Reaction A reaction that occurs when an antibody combines with a corresponding antigen to produce an immune complex causing agglutination of red cells.

5.2. Procedure Steps

- 5.2.1. Allow the test cell reagents and samples to reach room temperature before use.
- 5.2.2. Arrange the bench and perform quality control on reagent red cells.
- 5.2.3. Check all blood specimen and their identity (Patient's names and patient's number)
- 5.2.4. Centrifuge the specimen for 5 minutes at 3000 rpm.
- 5.2.5. Label 10 tubes 1 to 10 and sample number.
- 5.2.6. Dilute plasma/serum in serial dilution of 2 as follow:
 - a. Pipette 200ul normal saline to all 10 tubes.
 - b. Pipette 200ul patient serum/plasma to the tube No 1.



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- c. Mix tube no 1 and pipette 200ul of diluted serum/plasma from tube 1 to tube 2 mix and pipette 200ul mixed plasma from tube 2 to tube 3 and so on to tube 10.
- d. Pipette out 200ul diluted plasma from tube 10 and keep in a tube as 10+ to be used if needed for further dilution.
- e. In this dilution tubes represent the titer as follow:

| Tube No | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|----------|-----|-----|-----|------|------|------|-------|-------|-------|--------|
| Dilution | 1/2 | 1/4 | 1/8 | 1/16 | 1/32 | 1/64 | 1/128 | 1/256 | 1/512 | 1/1024 |
| Titer | 2 | 4 | 8 | 16 | 32 | 64 | 128 | 256 | 512 | 1024 |

- **Significant Titer Equal or more than 32 for Anti-D.**

5.2.7. Pipette reagent cells (having antigen for corresponding anti body or the cells by which IAT was positive) 100ul to each 10 tubes.

5.2.8. Mix and incubate at 37°C for 60 minutes.

5.2.9. Wash the cells in 10 tubes 3 time, decant all saline and add 4-5 (200ul) drops of Antihuman globulin serum, mix and centrifuge.

5.2.10. Read the tube for agglutination; the last tube showing +1 macroscopic agglutination represents the titer of antibody.

5.2.11. Record the result.

5.2.12. Add 1 drops of coombs check cell to all negative reaction tubes.

5.2.13. Mix, centrifuge and read the results. All negative reactions must be positive. In case of a negative reaction, repeat all



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procedure from beginning. Look errors in cell washing or additions of coombs serum.

5.2.14. Read and record the result :(**Example**); if last positive tube is tube no. 4, so the Titer is: 16.

5.2.15. **Reference value:** Normal: Less than 32 Significant Equal or more than 32 for Anti D.

6. Responsibility:

6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately.

6.2 It is the responsibility of assigned physician to assure implementation of policy and procedure.

7. References:

7.1 Technical Manual of American Association of Blood Banks, 18th edition 2014.

7.2 Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.

7.3 Leaflet from DiaMed Screening Cells.

7.4 Leaflet from DiaMed Coombs Control Check Cells.






7.5 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.6 CBAHI national standards for hospitals 3rd edition, 2015.



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8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 14-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> Thawing & Handling Of FFP & Cryoprecipitate. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-30 -V1 | <u>NUMBER OF PAGES:</u> 6 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide instructions to transfusion service laboratory staff to process thawing & handling of FFP & cryoprecipitate units in appropriate way.

2. Definitions:

2.1. Fresh Frozen Plasma (FFP): Plasma kept in freezer below -18 with in eight hours of collection is rich in Coagulation factors and fibrinogen and is known as Fresh Frozen Plasma.

2.2. Cryoprecipitate Antihemophilic Factor (AHF) is cold-insoluble portion cryoprecipitate (around 10 to 15 mL) harvested from Fresh Frozen Plasma. Each unit of cryoprecipitate should provides:

2.2.1. Fibrinogen 150–250 mg.

2.2.2. Factor VIII 80–150 U.

2.2.3. von Willebrand factor 100-150 U.

2.2.4. Factor XIII 50–75 U.

2.2.5. Fibronectin.



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3. Materials:

3.1. FFP /Cryoprecipitate Transfusion Request

3.2. EDTA Blood Specimen from, if ABO and Rh group of the patient is not known

4. Policy Statement:

4.1. It is the policy of transfusion services laboratory to provide safe and quality blood products to its clients.

4.2. It is the policy of transfusion services laboratory to ensure that the thawed Fresh Frozen Plasma (FFP) units are handled in an appropriate manner as follow:

- Thawed FFP units are prepared by thawing the FFP between 30 and 37°C without direct contact with the water.
- Thawed FFP units are stored under properly controlled conditions between 1 and 6°C.
- Thawed FFP units are transported in properly insulated container between 1 and 10°C.
- Thawed FFP units are assigned an expiration time of twenty four hours from the thawing time.
- Requirements for FFP preparation, storage, transport and expiration apply.



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4.3. It is the policy of transfusion services laboratory to develop policies and procedures to ensure that the thawed **CRYO units** are handled in an appropriate manner.

- a) Thawed CRYO units are prepared by thawing CRYO units between 30 and 37°C without direct contact with the water.
- b) Thawed CRYO units are stored and transported at room temperature (between 20 and 24°C).
- c) Thawed CRYO units are assigned an expiration time of six hours from the thawing time for individual units and four hours from the thawing time of pooled units.
- d) Requirements for CRYO preparation, storage, transport and expiration apply.

5. Procedure:

- 5.1.** Check the blood specimen and their identity (Patient's three names and patient's number).
- 5.2.** Perform the blood group and Rh factor for patient, if it is not known.
- 5.3.** You can receive the request without sample if, the blood group is done two times by two technician or one technician on two different samples.
- 5.4.** Select FFP unit or Cryoprecipitate AHF unit/s of similar or compatible to ABO and Rh group of the patient.



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- 5.5. Bring the selected units from freezer.
- 5.6. Record FFP/Cryoprecipitate unit numbers on the request.
- 5.7. Put them in the wrapping bags and hang in thawing bath.
- 5.8. Change thawing time to 5 minutes.
- 5.9. Remove thawed FFP/Cryoprecipitate as soon as the machine stops.
- 5.10. Dry FFP/Cryoprecipitate units if there is some moisture.
- 5.11. Put a label on the unit to assure proper expiry date from thawing time (24 hour for FFP & 6 hour for cryoprecipitate).
- 5.12. Affix labels correctly according to unit number.
- 5.13. Put a tag to the unit.
- 5.14. Keep the thawed FFP in the fridge until issue, Cryoprecipitate should be kept on bench until release or discard after 6 hours.
- 5.15. Hand over to reception to issue to the ward.

6. Responsibility:

- 6.1. It is the responsibility of transfusion service laboratory technician/technologist to perform the job.
- 6.2. The physician assigned in transfusion service laboratory is responsible for observation of proper release of blood products.

7. References:

- 7.1. Transfusion Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.








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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

- 7.2. Technical Manual of American Association of Blood Banks 18th Edition, 2014.
- 7.3. AABB Standards, 30th edition, 2016.
- 7.4. CBAHI National Standards for Clinical Laboratory & Blood Banks, 2015.
- 7.5. CAP Checklist TRM 2016.



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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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|---|--|--|-------------------------------------|
| <u>TITLE</u> Daily Quality Control For Antisera. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB -31 -V1 | <u>NUMBER OF PAGES:</u> 6 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to guide transfusion service lab staff to perform quality control for antisera daily.

2. Definitions:

2.1. Laboratory Quality Control: Quality control is a measure of precision or how well the measurement system reproduces the same result over time and under varying operating conditions.

2.2. Reagents are "substances or compound that is added to a system in order to bring about a chemical reaction or is added to see if a reaction occurs ". Such a reaction is used to confirm the presence of another substance.

3. Policy Statement:

3.1. It is the policy of transfusion service lab to develop a system for reagents quality control as follow:

- a. To ensure performance of reagents quality control on each day of use.
- b. To ensure anti-sera are checked against known positive and negative cells.
- c. to ensure reagent Red Blood Cells are checked against known positive and negative anti-sera.



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- d. To ensure results are checked against predefined acceptable results.
- e. To ensure results are reviewed and reagents are approved before use for patient testing.
- f. To ensure that Corrective actions are taken for unacceptable results.

3.2. It is the policy of transfusion service lab to perform quality control for reagent and validate results before starting used in routine work.

4. Materials:

4.1. Routine blood grouping reagents, consisting of:

- 4.1.1. Anti-A, Anti-B
- 4.1.2. Anti-D
- 4.1.3. A₁, B and O Negative Cells.
- 4.1.4. 12 x 75 mm test tubes

4.2. Serologic Centrifuge

4.3. Reagent Quality Control Record Sheet.

5. Procedure:

5.1. Locate the Reagent quality control record sheet. Fill out Record Sheet, record lot number, expiry date.

5.2. Under "Reagent Identification," record the manufacturer, lot number, and expiry date of the reagents in use.



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5.3. Examine the visual appearance of the reagents in use for hemolysis, turbidity, discoloration; etc. If the visual appearance is satisfactory, under "Reagent Appearance" write clear in the appropriate column.

5.4. If the visual appearance is NOT satisfactory, under "Reagent Appearance" write turbid in the appropriate column and replace the reagent. Make a note of the change in the "Result" section.

5.5. Label nine (9) 12 x 75 mm test tubes from 1 to 9 and dispense antiserum and cells as below:

| | Anti A | Anti B | Anti D |
|------------------|--------|--------|--------|
| A Cells | 1 drop | 1 drop | 1 drop |
| B Cells | 1 drop | 1 drop | 1 drop |
| O Negative Cells | 1 drop | 1 drop | 1 drop |

5.6. Mix all tubes and centrifuge for time indicated on centrifuge (20 seconds). Examine macroscopically for agglutination and record on the Record Sheet. Grade reactions according to Grading of Serological Reaction Policy.



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APPLIES TO: Transfusion Service Laboratory staff.

5.7. Interpretation/Expected Results

5.7.1. Interpret the result as table below

| | Anti A | Anti B | Anti D |
|------------------|--------|--------|----------|
| A Cells | 4+ | 0 | 3+ to 4+ |
| B Cells | 0 | 4+ | 3+ to 4+ |
| O Negative Cells | 0 | 0 | 0 |

5.8. Corrective Action: IF result does not correspond to the expected result.

- 5.8.1. Verify your procedure
- 5.8.2. Repeat the test with new reagent vials and cells
- 5.8.3. If result is still unsatisfactory, do not proceed to routine work.
- 5.8.4. Call the supervisor to look into the matter
- 5.8.5. If required inform medical director and chief technician to coordinate with the supplier.
- 5.8.6. Tests performed with these reagents are not valid unless the quality control results are acceptable.

5.9. Record Sheets will be retained for 5 years.



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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

6. Responsibility:

6.1. It is responsibility of all transfusion service lab staff to perform the procedure & responsibility of the senior technologist to review, date and initial each record sheet at the end of each week.

6.2. It is the responsibility of transfusion service lab physician to insure proper implementation of procedure.

7. References:

7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.

7.2. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.


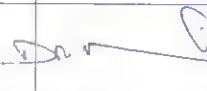

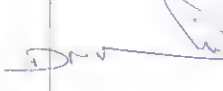

7.3. CBAHI national standards for hospitals 3rd edition, 2015.

7.4. CAP Checklist TRM, 2016.



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| <u>TITLE</u> Daily Quality Control For Antisera. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 14-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



TITLE Quality Control Procedure For ID DiaMed Cards And Cells.

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APPLIES TO: Transfusion Service Laboratory staff.

1. Statement Of Purpose:

The purpose of this policy is to assure accurate and specific results for transfusion service testing & to provide instruction to perform quality control procedure for ID DiaMed cards and cells.

2. Definition:

2.1. Quality Control: Testing routinely performed on materials and equipment to ensure their proper function.

3. Materials:

3.1. DiaMed Basic Q.C. Kit:

3.1.1. Sample 1: A negative, ccee K positive and containing anti-B and anti-D.

3.1.2. Sample 2: B positive, CcEe K negative and containing anti-A and anti-Fya.

3.2. ID A1 & B Cells

3.3. ID-DiaCells 1, 2 and 3

3.4. ID Incubator.

3.5. ID Centrifuge.

3.6. ID Gel Cards (ABO/D cards and Liss Coombs cards).

3.7. ID Diluent 2.

3.8. ID Micro Pipette.

3.9. Test Tubes.



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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

4. Policy Statement:

- 4.1. It is the policy of transfusion service laboratory staff to perform quality control for reagents daily before starting the routine work.
- 4.2. It is the policy of transfusion service lab to develop a system for reagents quality control as follow:
- To ensure performance of reagents quality control on each day of use.
 - To ensure anti-sera are checked against known positive and negative cells.
 - to ensure reagent Red Blood Cells are checked against known positive and negative anti-sera.
 - To ensure results are checked against predefined acceptable results.
 - To ensure results are reviewed and reagents are approved before use for patient testing.
 - To ensure that Corrective actions are taken for unacceptable results.

5. Procedure:

- Allow the test cell reagents and samples to reach room temperature before use.
- Check the QC sample 1 and QC sample 2.
- Centrifuge the specimen for 10 minutes at 3000 rpm.

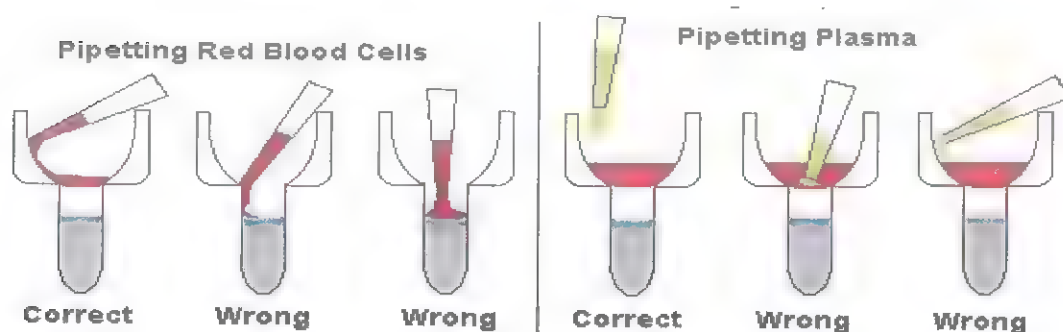
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5.4. Test Procedure for ABO D and Reverse Grouping:

5.4.1. Label ID ABO/D reverse card and test tube for cell suspension according to QC sample number.

5.4.2. Hold the card up right and remove the aluminum foil

5.4.3. Pipette the cell suspension and plasma as shown in picture below:



5.4.4. Pipette 50ul of ID DiaCell A to micro-tube labeled A1.

5.4.5. Pipette 50ul of ID DiaCell B to micro-tube labeled B.

5.4.6. Pipette 50ul patient plasma to micro-tube labeled A1 and B.

5.4.7. Prepare patients cell 5% suspension:

5.4.7.1. Dispense 0.5 ml ID Diluent II to a labeled test tube.

5.4.7.2. Add 25ul of PRBC from the centrifuged QC sample tube into diluent and mix.

5.4.8. Pipette 12.5ul of each QC sample suspension to the micro-tube labelled A, B, D and ctl.

5.4.9. Centrifuge the card for 10 minutes.



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5.4.10. Let centrifuge stop, take out the card, read and record the result.

5.5. Test Procedure for Antibody Screen:

- 5.5.1. Label ID Liss Coombs cards 3 micro-tubes for each QC sample, Cell 1, 2 and 3.
- 5.5.2. Pipette 50ul of ID DiaCell 1 to micro-tube 1, ID DiaCell 2 to micro-tube number 2 and so on cell 3 to tube 3.
- 5.5.3. Pipette 25ul of plasma of each QC sample to the labeled three microtubes.
- 5.5.4. Incubate the ID-Card for 15 minutes at 37 °C in the ID-Incubator.
- 5.5.5. After incubation centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.
- 5.5.6. Let centrifuge stop, take out the card, read and record the result.

5.6. Test Procedure for Rh-K phenotype:

- 5.6.1. Identify the ID-Card with the unique patient or donor number.
- 5.6.2. Prepare a 5% red cell suspension in ID-Diluent 2 as follows:
 - 5.6.2.1. Dispense 0.5 ml of ID-Diluent 2 into a clean tube.
 - 5.6.2.2. Add 50 µl of whole blood or 25 µl of packed cells, mix gently.



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5.6.3. Remove the aluminum foil from as many microtubes as required by holding the ID-Card in the upright position.

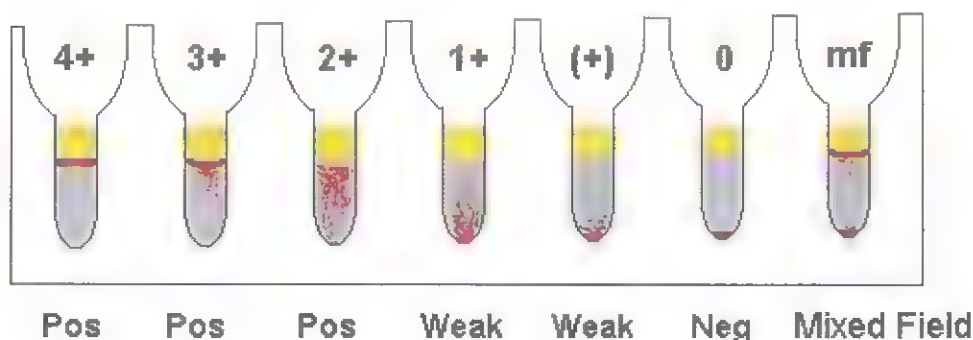
5.6.4. Add 10 or 12.5 µl of the patients' red cell suspension to all microtubes of the ID-Card.

5.6.5. Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.

5.6.6. Read and record the results.

5.7. Interpretation:

5.7.1. Interpret agglutination as follows:



5.7.2. For weaker reaction less than 3+ proceed to ABO/Rh Discrepancy policy.

5.7.3. Interpret ABO Grouping according to following table:

| Anti A | Anti B | Control | A Cells | B Cells | ABO Group |
|----------|----------|----------|------------|------------|----------------|
| 3+ to 4+ | Negative | Negative | Negative | 1+ to 4+ | A |
| Negative | 3+ to 4+ | Negative | 1+ to 4+ | Negative | B |
| Negative | Negative | Negative | 1+ to 4+ | 1+ to 4+ | O |
| 3+ to 4+ | 3+ to 4+ | Negative | Negative | Negative | AB |
| Positive | Positive | Positive | Pos or Neg | Pos or Neg | **Undetermined |



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5.7.4. Interpret Rh according to following table:

| Anti D | Control | Rh |
|--------------|----------|----------------|
| 3+ to 4+ | Negative | Positive |
| Less than +3 | Negative | *? |
| Negative | Negative | Negative |
| Positive | Positive | **Undetermined |

** proceed to weak d testing policy.

** proceed to determining blood group policy if control is positive.

5.7.5. Write result as Blood Group A Positive (As EXAMPLE).

5.7.6. Compare the reaction obtained with those on the enclosed table found in the QC kit. Record the results and take note of the lot number and expiry date of all reagents used.

5.7.7. Verify that the lot numbers indicated on the table correspond to the lot numbers on the vial labels.

5.8. Precautions:

5.8.1. Do not use ID-Cards which show signs of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper part of the microtubes or on the underside of the aluminum foil.

5.8.2. Bring ID diluent to room temperature before starting the work.

5.8.3. Pipette cell and serum as shown in the picture.



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5.9. Limitations of Procedure:

- 5.9.1. Bacterial or other contamination of materials used can cause false positive or false negative results.
- 5.9.2. Fibrin residues in the red cell suspension may trap non-agglutinated cells presenting a fine pink line on top of the gel while most of the cells are on the bottom of the micro-tube after centrifugation.
- 5.9.3. Use of suspension solutions other than ID-Diluent 2 may modify the reactions.
- 5.9.4. Too heavy or too weak red cell suspensions can cause aberrant results.

5.10. **Corrective Action:** If in any test or step result does not correspond to the expected result,

- 5.10.1. Check the cards if they are not dry or uneven.
- 5.10.2. Check your all procedure. Repeat the procedure. If the results are unsatisfactory in repeat test also, use another lot of cards and reagents.
- 5.10.3. Report to chief technician to manage the complaint with company.



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6. Responsibility:

- 6.1. It is the responsibility of assigned technician at transfusion service lab to perform the procedure daily.
- 6.2. It is the responsibility of assigned Physician to review the results.

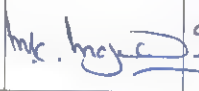




7. References:

- 7.1. Leaf let Diamed Basic Q.C.
- 7.2. Leaf let ID Gel Cards (ABO /D+Reverse and Liss Coombs).
- 7.3. Leaflet from ID Rh-K phenotype gel card.
- 7.4. CBAHI National Standards for Clinical Laboratory & Blood Banks, 2015.
- 7.5. CAP Checklist TRM, 2016.
- 7.6. Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.
- 7.7. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
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8. Approvals:

| | Name | Title | Signature | Date |
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| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
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| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> Visual Inspection Of Blood Components. | | | |
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1. **Statement Of Purpose:**

The purpose of this policy is to provide guidance to transfusion service laboratory staff to strictly observe Blood products before storage, release and issue or before accepting returned blood products or products from other hospitals for visual defects.

2. **Definitions:**

- 2.1. **Hemolysis** is the rupturing of erythrocytes (red blood cells) and the release of their contents (hemoglobin) into surrounding fluid (*e.g.*, plasma).
- 2.2. **Bacterial Contamination:** Growth of Bacteria in a blood component due to Contamination.
- 2.3. **Lipemia:** An excess of lipids (fats) in the blood product.
- 2.4. **Icterus:** the presence of jaundice (Higher bilirubin-yellow-green color) seen in the blood product.
- 2.5. **Discoloration:** Change in the colour of a blood product due to haemolysis, infection, icterus (yellow or green), oral contraceptives (green), vitamin A or large quantities of carrots (orange).
- 2.6. **Red cell in platelets units:** reddish color in platelets units due to improper separation for random donor platelet or during apheresis process for single donor platelet.

3. **Materials:**

- 3.1. Unit under inspection



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3.2. Pictures from Blood Component Visual Inspection Guide AABB, Red Cross.

4. Policy Statement:

4.1. It is the policy of transfusion service laboratory that each blood or blood component shall be inspected visually for suitability before release, at the time of issue and receive, a returned product or a product from other blood bank.

4.2. It is the policy of transfusion service laboratory that the red blood cells in random donor platelets or in apheresis platelets shall be ABO-compatible with the recipient's plasma and be crossmatched if the platelets component containing > 2 mL of red blood cells for apheresis platelets or > 1/2 ml for random platelets.

5. Procedure:

5.1. Product Label:

5.1.1. If the product expiry is a day date, the product expires at 23:59 h of that day.

5.1.2. Determine whether the product has been modified in the hospital/outside facility (pooled, modified, divided, etc.). If the product was modified, a date and time expiry label shall be attached to the product container. The label for modified or mixed components shall contain the:

a. Number of the units mixed or added



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- b. Name of the blood component added
- c. ABO and Rh groups of the donor units added.
- d. If the label is missing any information, including an expiry date and time, obtain the required information if available and correct the oversight.

5.2.3.Port(s) are intact.

5.3. Red Blood Cells (RBC) Products:

- 5.3.1.Inspect the red cell mass for the appearance of a purple or black coloration. If the red cell mass appears black or purple, suspect hemolysis in the unit. This may occur either by physical destruction of the red cells or by bacterial contamination.
- 5.3.2.Inspect the plasma or supernatant in PRBC for discoloration.
- 5.3.3.Bacterially contaminated plasma may appear a grayish murky color or appear purple or brown.
- 5.3.4.Quarantine the product and send for culture and stain to detect bacterial contamination. If the stain or culture detects bacteria write OVAR and discard the unit.
- 5.3.5.A bright red color may indicate significant red cell hemolysis.
- 5.3.6.For query hemolysed units; let the unit settle upright in blood holder for 24 h in fridge and observe the plasma carefully



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(ideally comparing to other units). Optional testing may include a plasma hemoglobin level.

5.3.7.If significant red cell hemolysis is noted, notify the transfusion service medical director, write OVAR and discard the unit.

5.3.8.Observe the unit for size (volume and weight). Discard the unit, Write OVAR and notify transfusion service medical director.

5.3.9. Mix the unit and observe for large clots. If large clots are found. Discard the unit, write OVAR and notify transfusion service medical director.

5.3.10. Red cell products that meet visual inspection criteria are suitable for processing in receipt into inventory, shipping to another facility, issue for transfusion purposes.

5.4. Platelet and Plasma Products:

5.4.1. Observe the red blood cells in platelets units, if the platelets component contains > 2 mL of red blood cells for apheresis platelets or <1/2 ml for random platelet, compatibility test with recipient's plasma must be done.

5.4.2. Inspect platelets for the presence of excess aggregates. If present, obtain authorization from a Medical Director to designate to use or not.

5.4.3. Check the platelets for swirling, if there is no swirling discard the unit.



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5.4.4. If Platelet concentrate unit has air bubbles in it, discard it.

5.4.5. Inspect for discoloration.

- a. Bacterially contaminated plasma may appear a grayish murky color or appear purple or brown.
- b. Quarantine the product and send for culture and stain to detect bacterial contamination.
- c. If the stain or culture detects bacteria write OVAR and discard the unit.
- d. If plasma is frozen, inspect the bag for signs of breakage if the unit is broken, discard the unit.

5.4.6. Plasma/Platelet products that meet visual inspection criteria are suitable for processing in receipt into inventory, shipping to another facility, or issue for transfusion purposes.

5.4.7. Blood components with lipemia (milky white appearance) are acceptable for transfusion.

5.5. Discard all products to be discarded and record in the form Discard for Different Reasons.

6. Responsibility:

6.1 It is the responsibility of transfusion service staff assigned to work in blood products storage, release, x-match, issue and receive the blood products to comply with the policy and procedure; compliance to this will be monitored by lab director.



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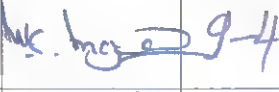




7. References:

- 7.1 Technical Manual American Association of Blood Banks, 18th edition, 2014.
- 7.2 Guide lines for the blood transfusion services UK 2008.
- 7.3 Blood Component Visual Inspection Guide AABB.
- 7.4 CBAHI National Standards for Clinical Laboratory & Blood Banks, 2015
- 7.5 CAP Checklist TRM, 2016.
- 7.6 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.7 CBAHI national standards for hospitals 3rd edition, 2015.



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8. Approvals:

| | Name | Title | Signature | Date |
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TITLE Issue of Blood Products After Compatibility Testing.

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1. Statement of Purpose :

The purpose of this policy is to provide instruction to all transfusion service laboratory staff to issue the blood components to patients after pre-transfusion compatibility testing.

2. Definitions :

2.1 Blood order /request: is a physician's prescription to transfuse a blood product to a patient.

3. Equipment / Material /Forms :

3.1 Blood release request from the physician.

3.2 Reports of pre-transfusion compatibility testing.

3.3 Blood components release log book.

4. Policy Statement :

4.1 It is the policy of transfusion service lab to develop a process for the issue of blood/blood component for transfusion as follow:

4.1.1 There is a process for the issue of blood/blood component to ensure accurate identification of the intended recipient and the required blood components.

4.1.2 The process ensures the integrity of the donor unit identification label and the recipient identification label.

4.1.3 The process ensures confirmation that the donor's ABO/Rh is identical with the recipient's, or marked compatible.

4.1.4 The process ensures proper documentation of the release event.



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4.2 It is the policy of transfusion service lab to issue a blood or its product for transfusion if ordered by a physician.

4.3 It is the policy of transfusion service lab to hold blood for 24 hours after pre-transfusion compatibility testing unless informed by the ward for maximum extension for further 24 hours. All reserved blood shall be cancelled and returned to inventory after 24 hours.

4.4 It is the policy of transfusion service lab that blood product shall be issued to only medical /paramedical staff or a trained blood porter.

4.5 Blood shall be issued only if the porter shall have a cooler.

5. Procedure :

5.1 Receive the blood release request from porter.

5.2 Check patient's information on the request i.e. patient full name, medical record number and name of the ward.

5.3 Check request is signed by a physician.

5.4 Check required product are mentioned on it.

5.5 Take the patients request and pre-transfusion compatibility record from concerned file.

5.6 Verify pre-transfusing compatibility tests (ABO Rh group and antibody screen) are recorded and signed by a technologist /technician and interpretation of the cross-match is there.



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- 5.7 Take out compatible blood units from the refrigerator by observing unit numbers and blood group and patient information on tag.
- 5.8 Check patient identities are similar, patient name, medical record number and ward.
- 5.9 Check unit number with the compatibility testing record.
- 5.10 Check unit's blood group on unit label and unit blood group mentioned on compatibility report and patient blood group are same and compatible.
- 5.11 Inspect the unit visually for suitability especially integrity, clots or hemolysis.
- 5.12 Keep the blood in thermal container.
- 5.13 Record /enter all information in Blood products release log book and/or in computer system if available including patient identities, ward, unit numbers and time of release, name and signature of the porter receiving blood.
- 5.14 Issue compatibility report and copy of transfusion request with the blood product unit with its attached tag.

6. Responsibility:

- 6.1 It is the responsibility of staff (Assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately.
- 6.2 It is the responsibility of physician assigned in the area to assure implementation of policies and procedure.



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7. References:

- 7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.
- 7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.
- 7.3. Leaflet from DiaMed for ID Liss Coombs Cards and ID Anti D.
- 7.4. Pictures provided by DiaMed for accurate pipetting procedure and grading the reactions.
- 7.5. Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.
- 7.6. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.7. CBAHI national standards for hospitals 3rd edition, 2015.



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8. Approvals:

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| <u>TITLE</u> Receiving Un-Transfused Blood Products. | | | |
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1. Statement Of Purpose:

The purpose of this policy is to provide instructions to all transfusion service staff to receive un-transfused blood products from our clients.

2. Definitions

2.1.Blood Order/Request Cancellation: is a physician's order to cancel transfusion of a blood product to a patient.

3. Equipment / Material /Forms :

3.1.Blood Return form.

3.2.Thermal Cooler.

3.3.Blood Return Request.

4. Policy Statement:

4.1.It is the policy of transfusion service staff to provide safe and quality blood products to its clients.

4.2.It is the policy of transfusion service staff that blood products shall be returned to blood bank only by medical/paramedical staff or a trained blood porter.

4.3.It is the policy of blood bank to receive blood **within half hour** from the time of issue unless the returning facility/ward has a temperature monitored blood storage refrigerator available, and a responsible person there to observe proper storage of blood and its products.



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4.4.It is the policy of blood bank to assure that the whole blood, PRBC/thawed FFP temperature is not more than 10°C and not less than 1°C and Platelet Concentrate temperature is not more than 24 °C and not less than 20 °C during transport.

4.5.Blood shall be received only if the blood is returned in a thermal cooler meeting the requirement of blood transport policy.

4.6.If above criteria is not met, blood unit shall not be accepted or accept and discard.

4.7.An OVAR shall be written and handed over to lab director to submit to the concerned department.

5. Procedure

5.1. Receive the blood return request from our clients through a trained porter.

5.2. Check Patient information on the request i.e. Patient's full name, patient's file number, name of the ward and blood component information (Unit number, blood group, expiry date) is there. Check that the physician's signature is there.

5.3. Verify that blood component information on the request and on the unit are same.

5.4. Returned units must not be reissued for transfusion unless the following conditions are met:



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5.4.1. The container closure has not been penetrated or entered in any manner.

5.4.2. Red cell components have been maintained continuously 1-10°C and platelet concentrate at 20-24°C.

5.4.3. The ports on the unit must be intact, and all labeling on the unit must be intact.

5.4.4. At least one sealed segment of integral donor tubing remains attached to the red cell component.

5.4.5. If acceptable, keep the unit in ready to use PRBC/ (FFP thawed) in transfusion service laboratory fridges.

5.4.6. Record blood components return in the log book in front of issue entries of these products and on computer system if available.

6. **Responsibility:**

6.1. It is the responsibility of assigned technician or technologist to accept the returned blood, keep it in the refrigerator and or enter in the computer program if available.

6.2. It is the responsibility of assigned physician to assure implementation of policies and procedure.

7. **References**






7.1. Technical Manual of American Association of Blood Banks 18th Edition, 2014.

7.2. AABB Standard 30th Edition 2016.



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8. Approvals:

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| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> Emergency And Uncross Matched Blood Transfusion. | | | |
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1. **Statement Of Purpose**

The purpose of this policy is to provide instructions to all transfusion service staff to issue blood and its components following proper criteria in case of emergency.

2. **Definitions**

- 2.1. **Release:** the act of assessing a blood component and making it available for use.
- 2.2. **STAT:** refers to a procedure that is to be performed immediately.

3. **Equipment / Material /Forms :**

- 3.1 Transfusion request and sample acceptable according to accepting transfusion requests and determining specimen suitability procedure.
- 3.2 EDTA Blood Specimen from Patient.
- 3.3 Physician call to issue the blood without sample.
- 3.4 Transfusion service lab call receiving log.

4. **Policy Statement:**

- 4.1 It is the policy of transfusion service lab to have a process for emergency release of uncross-matched or incompletely cross-matched blood as follow:



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- 4.1.1 There is a process for emergency release of uncross-matched or incompletely cross-matched blood that ensures a proper ordering procedure and required ordering information.
- 4.1.2 The process considers age and sex factors.
- 4.1.3 The process ensures ABO/Rh-D and labeling of the selected blood.
- 4.1.4 The process ensures subsequent compatibility testing and notification of the results.
- 4.1.5 The process ensures documentation of the release event (including the ordering physician signature).
- 4.2 It is the policy of transfusion service lab to accept a blood or its product transfusion request only if it is ordered by a physician.
- 4.3 Stat transfusion requests with complete pre-transfusion compatibility testing shall be finalized within 45 minutes to 60 minutes from receipt of request.
- 4.4 Maximum 1-2 O Negative PRBC units shall be released within 3-5 minutes without pre-transfusion compatibility testing in case of a stat request from treating physician, without sample, on physician's responsibility. Pre compatibility testing shall be completed after releasing the units and in case of any discrepancy, physician shall be informed urgently to stop the transfusion.



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4.5 Required urgent blood units shall be released within 10-15 minutes by immediate spin cross-match without anti body screen or complete cross-match, on the responsibility of treating physician. Antibody screen by 3 cell panel, and immediate spin cross match shall be performed immediately after issuing the units and in case of any discrepancy, lab medical director and physician shall be informed urgently to stop the transfusion.

5 Procedure

5.1 Request without sample:

5.1.1 Written request shall be received accordingly.

5.1.2 If no written request and the physician is calling to issue the blood without request and sample, take the following information's from the physician and record it in the transfusion service lab call receiving log.

5.1.3 Physician's name, his ID number, extension phone number, and department from where he needs the blood.

5.1.4 Patient's three names and file number, if available.

5.1.5 Ask the physician to send the porter.

5.1.6 Request the physician to send regular request as soon as possible with remarks to send blood without sample.

5.1.7 Request the physician to provide the patient's blood sample as soon as possible before transfusion.



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5.1.8 Send 1-2 units, according to physician's request, O Negative PRBC, record numbers in work sheet, detach one segment from each unit and keep in labeled tubes.

5.1.9 Record in issue log book or in computer system if available.

5.1.10 Send the blood quickly; process must be finished within 3-5 minutes.

5.1.11 Perform blood group from the segments and keep the segment suspensions to continue the work if sample received, if any discrepancy arise in the blood grouping, inform the physician and blood bank medical director.

5.2 On receipt of patient sample

5.2.1 Perform the blood group and Rh factor for patient according to blood grouping policy.

5.2.2 Perform anti body screen according to antibody screening policy.

5.2.3 Check patient transfusion/antibody screen/Blood grouping history.

5.2.4 If any discrepancy arises inform the physician and lab director.

5.2.5 If physician requires further blood products, issue blood patients group specific by immediate spin cross match, as the patient has no unexpected antibodies.

5.2.6 If patients antibody screen reveals positive, inform physician and lab director and start the antibody identification procedure mean



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while physicians may decide the course of transfusion on their responsibility if the stat transfusion is required.

5.3 Multiple Stat Transfusion Patients at a Time (Disaster).

5.3.1 Inform lab director/chief technician of the situation.

5.3.2 Let more than one technician arrange their benches and be ready to receive and issue/test blood units quickly & Issue uncross-matched O Negative or Positive red cells.

5.3.3 Let technicians to prepare suspension from O+, A+, and B+ PRBCs units for immediate spin and keep ready.

5.3.4 Process the requests according to above procedures accordingly.

5.3.5 If similar Blood Group not available select alternate blood group as follow:

| Patients | 1st Choice | 1st | 2nd | 3rd |
|-----------------------|------------------------------|-------------------------|-------------------------|-------------------------|
| Blood Group | Similar Group | Alternate Choice | Alternate Choice | Alternate Choice |
| O | O | No Choice | No Choice | No Choice |
| B | B | O | No Choice | No Choice |
| A | A | O | No Choice | No Choice |
| AB | AB | A | B | O |
| Rh Positive | Rh Positive | Rh Negative | No Choice | No Choice |
| Rh Negative | Rh Negative | *No Choice | No Choice | No Choice |
| ABO | O (red Cells) | No Choice | No Choice | No Choice |
| Discrepancy | AB (FFP/Plts) | | | |
| Rh Discrepancy | Rh Negative products | No Choice | No Choice | No Choice |

* If a life threatening condition arises; Patient's physician and assigned lab physician may decide to transfuse Rh Positive blood to Rh Negative patient once in a patient life.



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5.4 Shifting The Patient To Blood Group Specific Transfusion

- 5.4.1** Shift the patient to his blood group as soon as his blood specimen is received and blood group is determined.
- 5.4.2** If patient has taken more than 8 units of his Nonspecific ABO compatible Blood Group PRBC or 2 units of nonspecific blood group FFP, perform AHG and IS cross-match, or continue the nonspecific blood group transfusion.

6 Responsibility

- 6.1** It is the responsibility of assigned technician/technologist to perform the job.
- 6.2** The assigned physician is responsible for observation of proper processing of blood products request.

7 References

- 7.1** Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.
- 7.2** Technical Manual of American Association of Blood Banks 18th Edition, 2014.
- 7.3** AABB Standards, 30th edition, 2014.
- 7.4** The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.5** CBAHI national standards for hospitals 3rd edition, 2015.



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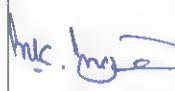




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APPLIES TO: Transfusion Service Laboratory staff.

8. Approvals:

| | Name | Title | Signature | Date |
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| <u>TITLE</u> Release Of Incompletely Tested Blood/Blood Components For TTD. | | | |
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1. Statement Of Purpose:

The purpose of this policy is to develop a guide lines to issue or release of incompletely tested blood/blood components for TTD diseases in case sever emergency/Disaster.

2. Definitions:

- 2.1. Transfusion Transmitted Disease (TTD):** a disease transmitted by a blood product from an infected donor to its recipient.
- 2.2. Disaster:** a sudden misfortune or calamity causing widespread distress or misery or loss of life. The disaster may be locally, regionally, nationally or internationally.
- 2.3. Stat/emergency Blood Transfusion:** Transfusing blood products to a patient in short notice when patient is in a life threatening condition.
- 2.4. Incompletely tested Blood Products:** In terms of this policy, **incompletely** tested blood products define a blood product whose pilot sample is incompletely tested or under testing procedure for all or any of the serological tests mandated by MOH.

3. Equipment/Material/Forms:

- 3.1.** All requirement according to relevant transfusion service policies & procedures.



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3.2. Data entry forms/log books.

3.3. Required Blood Products.

4. Policy Statement:

It is the policy of transfusion service laboratory to:

4.1. Issue blood products to all patients after completing all necessary tests mandated by Ministry of Health Saudi Arabia.

4.2. Issue **incompletely tested** blood product for all or any serological tests must fulfil the following conditions:

4.2.1. Tested blood products are not available in transfusion service laboratory.

4.2.2. Transfusion service laboratory has tried its best to arrange tested blood products from other hospitals by requesting/contacting all nearby hospitals.

4.2.3. In direct emergencies, patient/family signs consent for "transfusion without NAT testing.

4.2.4. For urgent need only; Non Transfusion of blood might be life threatening for the patient and his condition doesn't not allow to complete the testing procedure.

4.2.5. Upon the discretion of the medical director of the transfusion medicine, the agreement of the attending



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physician and the consent of the patient or next of kin, when applicable.

4.2.6. Approved only for a particular patient and one transfusion event.

4.2.7. Patient's physician requests to issue incompletely tested blood products.

4.2.8. The released blood products are conspicuously labeled to this effect.

4.2.9. Testing of the blood/blood components must be completed and reported promptly to the attending physician.

4.2.10. Transfusion service laboratory shall reports any positive/reactive test result as Critical Result.

4.2.11. Transfusion service laboratory shall generates a Sentinel Event OVAR if any positive/reactive blood product is transfused.

4.2.12. Transfusion service laboratory shall complete all pre transfusion compatibility testing requirements before issuing the products if patient's physician allow the required time.

5. Procedure: NA.



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6. Responsibility:

- 6.1. It is the responsibility of transfusion service laboratory director or assigned physician to accept or reject any such decision depending upon patient's condition and available facilities in transfusion service laboratory.
- 6.2. Transfusion service laboratory director shall take any decision in consultation with treating physician.

7. References:

- 7.1. Technical Manual of American Association of Blood Banks, 18th edition 2014.
- 7.2. The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.3. CBAHI national standards for hospitals 3rd edition, 2015.



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8. Approvals:

| | Name | Title | Signature | Date |
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| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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1. Statement Of Purpose:

The purpose of this policy is to provide instructions to blood transfusion laboratory to issue blood products following proper criteria in massive transfusion event.

2. Definitions:

2.1.Blood Order/Request is a physician's prescription to transfuse a blood product to a patient.

2.2.Blood Volume: One blood volume is approximately 5000 mL or 70 mL/kg in a 70 kg adult.

2.3.Massive Transfusion Event (MTE): Transfusion of a volume of blood components equivalent to a patient's estimated total blood volume:

a- Administration of about **8-10 units** or more PRBCs in adults, **within a 24 hour period.**

b- Other definition as acute administration of **4 to 5 PRBCs units in 1 hour.**

2.4.Massive Transfusion Protocol (MTP): A protocol developed to ensure rapid recognition, response, and intervention for those patients experiencing a massive transfusion event. A MTP is activated when the health care provider anticipates the hemorrhage event will require massive transfusion support.



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3. Materials:

- 3.1. Transfusion Request with or without EDTA Blood sample.
- 3.2. Blood Coolers.
- 3.3. Verbal request form.
- 3.4. Thawed FFP (4 units).
- 3.5. O positive or O negative (4 units).
- 3.6. Platelets (6 units single or one apheresis unit).
- 3.7. Cryoprecipitate (10 units).

4. Policy Statement:

- 4.1. It is the policy of transfusion service laboratory to provide safe and quality blood products to its MTP's patients as soon as possible of the call/request/porter arrival. Policy & procedures of requesting blood products from other MOH health facility should be applied.
- 4.2. The issued component should be with a ratio 1:1:1 (Plasma: RBC: Platelets).
- 4.3. In case of non-availability of any products, products shall be issued following policy & procedure of issuing of incompletely tested blood, particularly platelets without bacterial detection.
- 4.4. To avoid misuse and wasting of blood products and avoid unnecessary blood transfusion reaction, the MTP process should include in-process assessment of coagulopathy, acidosis,



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hypothermia, hypocalcemia and consulting of hematology clinician if indicated.

5. Procedure:

- 5.1. The assigned physician/nurse in the ER/ Other Department is responsible to activate the MTP based on the clinical criteria specified for that.
- 5.2. The assigned physician/nurse has to contact transfusion laboratory assigned technologist /physician or lab director through the specified telephone number which in turn implements procedures of requesting blood products from other MOH health facility
- 5.3. The assigned physician /nurse provides his full name and ID to the laboratory call receiver.
- 5.4. Provides also medical record number, sex, name, age & location of patient.
- 5.5. The laboratory call receiver has to read back and records the data he received in the specified form.
- 5.6. Once the assigned responsible qualified person reach to transfusion service lab to take the cooler, he has to stamp the verbal order request as an acknowledgment that data received by verbal order are correct.



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5.7. The assigned technician/technologist has to hand over the 1st MTP cooler to the assigned responsible qualified person immediately which contain:

5.7.1. Four uncrossmatched universally compatible PRBC units (O Rh-negative if female patient* and O Rh-positive if male patient).

* N.B. For MTP female patient more than 50 years old; O positive can be issued safely, but for female patient less than 50 years old if O negative unavailable, O positive can be issued only after permission from treating physician.

5.7.2. Four thawed AB plasma units.

5.7.3. One Apheresis platelets unit (preferable AB negative if female or AB positive if male or any group for both gender*), or 6 random platelets.

5.7.4. Cut, label and keep the segment of issued PRBC

5.7.5. Register all unit numbers and segment numbers of PRBCs in the specified form

* N.B. Rh Immune globulin should be administered to female under 50 years old who are Rh negative who have received Rh positive platelets, the recommended standard dose is 300µg can cover 30 units' platelets.

5.8. Written MTP request with two pretransfusion EDTA blood samples shall be received following the verbal order request.



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5.8.1. Start pretransfusion compatibility tests on issued PRBCs once received patient's pretransfusion samples following relevant policy & procedures.

5.8.2. Register the data of the issued units and the finding of the pretransfusion compatibility tests.

5.8.3. In case of any discrepancy like antibody screen positive:

5.8.3.1. Inform the transfusion lab medical director or physicians urgently.

5.8.3.2. If no physician available, inform transfusion lab director.

5.8.3.3. If no one available inform the ward/doctor directly.

5.8.3.4. Transfusion lab medical director/physician/director shall immediately contact the treating team to initiate corrective action and proper course of transfusion to follow.

5.9. The 2nd MTP products' cooler should contain such number of components as in 1st set but of the group specific or group compatible to the patient, in addition to ten cryoprecipitate units of any group.

5.10. The 2nd MTP products' cooler should be ready to issue after maximum one hour of the 1st set releasing after completing all required pretransfusion tests corresponding to written request.



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5.11. The 3rd MTP products' cooler should be ready to issue after maximum one hour of the 2nd set releasing after completing all required pretransfusion tests corresponding to written request.

5.12. If patient has taken more than 8 units of his non-group specific ABO compatible blood group PRBC, perform AHG and IS x-match, or continue the non-specific blood group transfusion.

5.13. The assigned physician/nurse in the department is responsible update the transfusion lab assigned technician/technologist by any changes in the patient's location or data

5.14. The assigned physician/nurse in the department will call transfusion lab to terminate the MTP.

6. Responsibility:

6.1. It is the responsibility of transfusion lab technician/technologist to deal with MTP events.

6.2. The physician assigned in the transfusion lab is responsible for observation of proper processing of blood products in MTP event and determine any deviation needed.



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7. References:

- 7.1 ACS TQIP MASSIVE TRANSFUSION of American Collage of Surgeon.
- 7.2 Technical Manual of American Association of Blood Banks 18th Edition, 2014.
- 7.3 AABB Standards, 30th edition, 2016.
- 7.4 CBAHI National Standards for Clinical Laboratory & Blood Banks, 2015.
- 7.5 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013
- 7.6 CAP Checklist TRM, 2016.



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8. Approvals:

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1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service lab staff to select proper red cells unit and test for infant less than 4 months and guidance for neonatal exchange transfusion.

2. Definitions

2.1 Neonates: In transfusion medicine, an infant (new born child) is considered neonate till he reaches 4 months of age.

2.2 Neonatal Exchange Transfusion is the introduction of whole blood in exchange for 75-85% of an infant's circulatory blood that is repeatedly with drawn in small amounts and replaced with equal amount of donors blood.

2.3 Hemolytic Disease of Fetus and New Born: is the destruction of newborn's RBCs by maternal allo antibodies specific for inherited paternal red cells allo antigens.

2.4 Erythroblastosis Fetalis is a clinical condition characterized by agglutination and hemolysis of RBC usually due to incompatibility between infant's blood and that of the mother's like Rh or ABO etc.



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3. Equipment/Material/Forms:

- 3.1.** EDTA blood specimen baby and mother/ baby only.
- 3.2.** All equipment's and forms used in forward grouping and cross matching procedure.
- 3.3.** Welder Machine.

4. Policy Statement:

4.1.If The Transfusion Service Laboratory Have Not Welder Machine:

policy and procedures of requesting blood products from other MOH health facility should applied.

4.2.It Is Policy of transfusion service lab to define Neonatal testing and transfusion that entails determination of the neonate ABO/Rh and conditions for repeat of ABO/Rh testing as follow:

- a. The process entails performance and interpretation of Direct Anti-globulin Test (DAT).
- b. The process describes conditions for omitting re-typing and serological cross-match.
- c. The process considers the clinically significant antibodies of maternal origin.
- d. The process describes selection of RBC and plasma components for top-up, exchange and intrauterine transfusions.



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4.3 It Is Policy Of Transfusion Service Lab To Perform Special Considerations For Neonates As Follow:

- 4.3.1** It is the policy of transfusion service lab to provide fresh (maximum 14 days old) blood aliquot.
- 4.3.2** An initial pretransfusion sample shall be tested to determine ABO group and Rh type. For ABO, **forward grouping only.**
- 4.3.3** The serum or plasma of either the neonate or the mother may be used to perform the test for **Ab screening.**
- 4.3.4** Repeat ABO grouping and Rh typing may be omitted for the remainder of the neonate's hospital admission or until the neonate reaches the age of 4 months, whichever is sooner.
- 4.3.5** If the initial screen for red cell antibodies is negative, it is unnecessary to cross-match donor red cells for the initial or subsequent transfusions.
- 4.3.6** If the initial antibody screen demonstrates clinically significant unexpected red cell antibodies, units shall be prepared for transfusion that either do not contain the corresponding antigen or are compatible by antiglobulin crossmatch until the antibody is no longer demonstrable in the neonate's serum or plasma.
- 4.3.7** If a non-group-O neonate is to receive non-group-O Red Blood Cells that are not compatible with the maternal ABO group, the neonate's serum or plasma shall be tested for anti-A or anti-B.



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4.3.8 Test methods shall include an antiglobulin phase using either donor or reagent A1 or B red cells.

4.3.9 If anti-A or anti-B is detected, Red Blood Cells lacking the corresponding ABO antigen shall be transfused.

4.4 It Is Policy Of Transfusion Service Lab To Perform Special Considerations For Neonatal Exchange As Follow:

4.4.1 It is the policy of transfusion service lab to provide fresh (less than 14 days), CMV free (filtered) whole blood for neonatal exchange transfusion.

4.4.2 It is the policy of transfusion service lab to perform complete cross match up to Anti Human Globulin for all patients having neonatal exchange transfusion.

4.4.3 It is the policy of transfusion service lab to perform antibody screen test for all patients requiring red blood cells transfusion.

4.4.4 Anti-body screening for all patients requiring antibody screen or pre-transfusion compatibility testing shall be performed using 3 cell panel of known phenotype by Indirect Anti Human Globulin test (IAT).

4.4.5 Transfusion request and sample receiving SOP shall be strictly followed.



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5. Procedure

5.1 procedure of neonatal pre-transfusion testing:

- 5.1.1** Perform the blood group and Rh factor for patient according to ABO and Rh grouping For Infant below 4 months.
- 5.1.2** Confirm Patients blood group from patient history, if blood group is not available in the history, re-check the blood group from same sample.
- 5.1.3** Perform anti body screen on first neonatal blood specimen according to antibody screening policy.
- 5.1.4 If antibody screen reveals positive**
 - a. Request mother's blood specimen for anti-body identification
 - b. Proceed to antibody identification
 - c. Perform phenotype to find relative antigen negative units from group O units with the same Rh group or alternate.
 - d. Select relevant antigen negative PRBC O Rh same as of the baby and if Anti D is detected, select Rh Negative O red cells even if the baby is Rh positive.
 - e. Check the units visually for Hemolysis, clots and proper labeling
 - f. Check the units' expiry date for validity.



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- g. Confirm Blood unit's blood Group
- h. Perform Complete cross-match (Coombs phase)
- i. Perform the complete cross- match for each following transfusion.

5.1.5 If antibody screen reveals negative

- a. Select O PRBC and Rh same as of child.
- b. If O red cells not available, select red blood cells similar to baby's ABO or an alternate and perform complete cross-match (or test baby's sample with A1 and B cells by coombs phase to detect any passive antibodies from mother, if antibody is detected, select relevant antigen negative blood.

5.1.6 Bring the pediatric unit from fridge.

5.1.7 Check the units visually for Hemolysis, clots and proper labeling.

5.1.8 Check the units' expiry date for validity.

5.1.9 Confirm blood unit's blood Group.

5.1.10 Finalize the request and give to receptionist to issue or file according to request.

5.1.11 No further testing is required for future subsequent transfusion for this single admission. If baby is discharged and re-admitted repeat all steps as a new patient. After ten days select another unit in the



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same way, no testing is required other than confirming ABO and Rh of the PRBC unit, if it is not done previously during cross match for single admission.

5.2 procedure of neonatal exchange testing:

- 5.2.1** Perform new born blood group and DAT.
- 5.2.2** Perform Anti body screening on baby or mothers sample.
- 5.2.3** Select Fresh (less than 14 days) O Negative or Rh same as of child and relevant antigen negative and WBC filtered PRBC unit.
- 5.2.4** If O red cells not available, select red blood cells similar to baby's forward ABO but you have to test baby's sample with A1 and B cells by coombs phase to detect any passive antibodies from mother, if antibody is detected, select relevant ABO antigen negative blood.
- 5.2.5** Perform AHG cross match.
- 5.2.6** Keep the unit ready.
- 5.2.7** Upon call from the ward for blood ready, assure for the transfusion.
- 5.2.8** Thaw one unit AB Fresh Frozen Plasma.
- 5.2.9** Centrifuge PRBC unit for 5 minutes at 4°C in refrigerated centrifuge.
- 5.2.10** Attach an empty transfer bag by sterilize tube connector.



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5.2.11 Transfer supernatant anticoagulant-Additive Solution/Plasma and seal the tube and detach the bag.

5.2.12 Connect AB thawed plasma bag with the PRBC bag.

5.2.13 Transfer AB FFP to PRBC, seal and detach the empty plasma bag.

5.2.14 Label on the unit and record on the document “Additive Solution Removed added AB Plasma unit Number.....”).

5.2.15 Change expiry date to 24 hours.

5.2.16 Issue the unit accordingly.

6. Responsibility:

6.1 It is the responsibility of staff (assigned technician or technologist) in transfusion service laboratory to perform the procedure accurately or request to prepare the neonatal unit from other MOH health facility if the welder not available.

6.2 It is the responsibility of physician assigned in the transfusion service laboratory to assure implementation of policy and procedure.

7. References:

7.1. Technical Manual of American Association of Blood Banks, 18thed 2014.

7.2. Transfusion, Service Manual of SOPs, Training Guides and Competency Assessment Tools 2nd edition.








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7.3. Standards for Blood Bank and Transfusion Services .Bethesda, MD:
American Association of Blood Bank 30th edition, 2016.

7.4. The unified Practical Manual for Blood Banks in Arab Countries (MOH)
2013.

7.5. CBAHI national standards for hospitals 3rd edition, 2015.

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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1. Statement Of Purpose:

The purpose of this policy is to provide instructions to all transfusion service laboratory staff to prepare small portions (Aliquot) from a blood unit for pediatric use.

2. Definitions:

2.1 An aliquot is a portion of a total amount of a blood bag.

3. Materials:

3.1. Primary Blood Bag.

3.2. Sterilize Tube Connecting (Welding) Device.

3.3. Wafers for TSCD (Terumo Sterilize Tube Connecting Device).

3.4. Sterilized Transfer Bag.

4. Policy Statement:

4.1. It is the policy of transfusion service laboratory staff to issue aliquot of blood for pediatric patients.

4.2. If The Transfusion Service Laboratory Have Not Welder Machine: policy and procedures of requesting blood products from other MOH health facility should applied.

4.3. It is the policy of transfusion service laboratory staff to issue a single unit for multiple pediatric patient.

4.4. Several aliquote from one O fresh (3-7 days) positive unit of PRBC shall be prepared kept ready for use for different pediatric patients. Older aliquotes more than 10 days from collection date shall be



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discarded and aliquotes from fresh units shall be prepared. O Negative units shall be divided on arise of need.

4.5. A PRBC units shall be reserved for a neonate if the treating physician informs transfusion service that the neonate is a candidate for multiple red cells transfusion hence aliquots shall be issued to him/her accordingly from the same unit.

5. Procedure:

5.1. If The Transfusion Service Laboratory Have Not Welder Machine: policy and procedures of requesting blood products from other MOH health facility should applied.

5.2. If The Transfusion Service Laboratory Have Welder Machine:

5.2.1 Bring primary bag to be divided (O+ or O Negative accordingly).

5.2.2 Bring Sterlize blood Transfer bag.

5.2.3 Check power of the TSCD is on.

5.2.4 Press reset.

5.2.5 Open the clumps and inserts tubes in the groves.

5.2.6 Press Start switch.

5.2.7 Wait for the beep and open the clump, remove extra tubes from the grove and discard in yellow waste bag.

5.2.8 Remove the welded tube gently from the grove.



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5.2.9 Check if the weld is complete, otherwise consider products open system and change the expiry date to 24 hours.

5.2.10 Press gently the welded place to open the line.

5.2.11 Transfer the required amount in the transfer bag.

5.2.12 Detach the bags after sealing the tubes.

5.1.13 Try to bring the welded area to be removed along with detached extra tubes.

5.1.14 Print and attach the tag paper.

5.1.15 Save the bags in relevant fridges.

6. Responsibility:

6.1. It is the responsibility of transfusion service technician working in the cross match area to request to prepare the aliquot from other MOH health facility if the welder not available OR prepare the aliquot if the welder available.

7. References:

7.1. Technical Manual of American Association of Blood Banks 18th Edition, 2014.

7.2. AABB Standards 28th edition 2016.

7.3. CBAHI National Standards for Clinical Laboratory & Blood Banks, 2015.

7.4. CAP Checklist TRM 2016.








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7.5.The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.

7.6.CBAHI national standards for hospitals 3rd edition, 2015.

8. Approvals:

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1. Statement of Purpose :

The purpose of this policy is to provide the transfusion service medical director as member in blood transfusion committee; about how to give instructions to other members of committee about Handling, Use, And Administration Of Blood Products to be monitored (by committee) on all levels; medical staff on patient side and on lab side.

2. Definitions :

2.1 Compatibility Label/Tag: tag or label attached to a blood component or blood product that has been designated for a specific recipient, specifying information that identifies the blood component or blood product for that recipient.

2.2 Transfusionist: individual who administers a blood transfusion.

2.3 Type and screen (T/S): Provide information about the patient's blood ABO group RH type and the presence of unexpected red cell antibodies.

2.4 Type and cross matched (T/C): Is an order a T/S plus request for a specified number of RBC units.

2.5 MSBOS: Maximum Surgical Blood Order Schedule.

3. Equipment / Material /Forms :

3.1 All other documents /Forms in the related policies.



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4. Policy Statement

4.1 It is policy of transfusion service to develop collaboratively with the blood utilization committee, policies & procedures of guiding the handling, use, and administration of blood and blood products which cover the following items:

4.1.1 Only physicians order blood and in accordance with a policy clarifying when blood and blood products may be ordered.

4.1.2 The physician obtain informed consent for transfusion of blood and blood products.

4.1.3 Elements of patient consent include:

- a) Description of the transfusion process.
- b) Identification of the risks and benefits of the transfusion.
- c) Identification of alternatives including the consequences of refusing the treatment.
- d) Giving the opportunity to ask questions.
- e) Giving the right to accept or refuse the transfusion.

4.2 Two staff members verify the patient's identity prior to blood drawing for cross match and prior to the administration of blood.

4.3 In direct emergencies, patient/family signs consent for "transfusion without NAT testing, policy & procedure of issuing of Incompletely Tested Blood should be applied.



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- 4.4 Blood is transfused according to accepted transfusion practices from recognized professional organizations.
- 4.5 Policies and procedures guide the administration of blood transfusions.
- 4.6 Patients receiving blood are closely monitored.
- 4.7 Transfusion reactions are reported and analyzed for preventive and corrective actions .policy & procedure of management of adverse transfusion reaction should be applied.
- 4.8 Side effects or complications are immediately reported to the medical staff and blood bank and the transfused unit is sent to the transfusion service lab for further investigations. Policy & procedure of management of adverse transfusion reaction should be applied.

5. Procedures

5.1 Blood transfusion ordering :

- 5.1.1 Only physicians order blood (policy & procedure of accepting transfusion requests and determining specimen suitability should be applied) and in accordance with a policy clarifying when blood and blood products may be ordered.
- 5.1.2 The blood utilization committee should all agree on the number of units required for each surgical procedure.



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5.1.3 Recommended Maximum Surgical Blood Usage:

| Procedure | Blood Units |
|------------------|--------------------|
|------------------|--------------------|

A. General Surgery

- | | |
|---------------------------|-----|
| 1. Breast Biopsy | T/S |
| 2. Colon resection | 2 |
| 3. Laparotomy exploration | T/S |
| 4. Gastrectomy | 2 |
| 5. Mastectomy, radical | T/S |
| 6. Pancreatectomy | 4 |
| 7. Splenectomy | 4 |
| 8. Thyroidectomy | 2 |
| 9. Parathyroidectomy | T/S |
| 10. Hasab Operation | 4 |
| 11. Hepatobiliary | 2 |

B. Vascular

- | | |
|-----------------------------------|-----|
| 1. Aortic bypass graft | 4 |
| 2. Endarterectomy | T/S |
| 3. Femoral-popliteal bypass graft | 2 |

C. Urology

- | | |
|---|---|
| 1. Trans urethral U.B. resection or prostatectomy | 1 |
| 2. Radical Nephrectomy | 3 |
| 3. Radical perineal Prostatectomy | 2 |
| 4. Renal Transplant | 2 |
| 5. Radical cystectomy | 3 |



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D. ENT

- | | |
|-----------------|---|
| 1. Laryngectomy | 2 |
|-----------------|---|

E. Thoracic Surgery

- | | |
|------------------------------------|-----|
| 1. Lung biopsy | T/S |
| 2. Lobectomy or Bilobectomy | 2 |
| 3. Thoracotomy | 2 |
| 4. Thoracotomy with decortications | 4 |
| 5. Pneumonectomy | 4 |
| 6. Rigid Thoracoscopy | T/S |
| 7. Oesophagectomy | 4 |
| 8. Pericardectomy | 2 |
| 9. Mediastinoscopy | T/S |

F. Cardiac Surgery

- | | |
|------------------------------|---|
| 1. Aneurism resection | 6 |
| 2. Coronary bypass (Redo) | 4 |
| 3. Coronary bypass (primary) | 2 |

G. Plastic Surgery

- | | |
|--------------------------------|-----|
| 1. Hemangioma | 2 |
| 2. Cleft Palate | T/S |
| 3. Pharyngioplasty | T/S |
| 4. Rhinoplasty and Septoplasty | 1 |
| 5. Abdominoplasty | 2 |
| 6. Mamoplasty | 2 |
| 7. Liposuction | 2 |
| 8. Bed sores | 1-2 |
| 9. Burn | 1-2 |
| 10. Head and neck | 1-4 |



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H. Neurosurgery

1. Craniectomy:

- | | |
|-------------------------------|---|
| a. Extra or subdural hematoma | 2 |
| b. Tumour excision | 2 |
| 2. Lumbar dissection | 1 |
| 3. Cervical dissection | 1 |
| 4. Spinal tumour excision | 2 |

I. Orthopedic Surgery

- | | |
|--|-----|
| 1. Arthroscopy, Laminectomy /knee replacements | T/S |
| 2. Cervical spine fusion and fixation | 2 |
| 3. Thoraco lumbar spine fusion and fixation | 2-4 |
| 4. Shoulder, Humeral or elbow surgery | 2 |
| 5. Total hip replacement | 3-6 |
| 6. DHS | 2-4 |
| 7. Femur shaft (plate or nail) | 2-4 |
| 8. Tibia (plate or nail) | 2 |
| 9. Debridement | 2 |
| 10. Pediatric CDH or Femur plating | 1 |

J. Dental Surgery

- | | |
|---|-----|
| 1. Reduction, fixation, biopsy, or cyst | T/S |
| 2. Coronidectomy | 1 |
| 3. Condylectomy | 2 |
| 4. Genioplasty | 1 |
| 5. Osteotomy | 2 |
| 6. Tumor Resection with reconstruction | 4 |



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k. Gynecology

| | |
|---|---------|
| Ectopic pregnancy (laparotomy or Laparoscopically) | 1 units |
| Ectopic pregnancy with shock | 4 units |
| Complicated Abdominal and Vaginal Hysterectomy | 2 units |
| Abdominal hysterectomy (by Laparoscopy) | 2 units |
| Radical Hysterectomy | 4 units |
| Radical vulvectomy | 4 units |
| Myomectomy | 2 units |
| Molar pregnancy | 2 units |
| Exploratory Laparotomy (Gyne) | 2 units |
| Simple hysterectomy | T/S |
| Ovarian cystectomy | T/S |
| Vaginal Prolapsed repair | T/S |
| Diagnostic Dilatation and Curettage | T/S |
| Evacuation | T/S |
| Cervical Cerclage | T/S |
| Cervical Polyp | T/S |
| Inevitable miscarriage | T/S |
| Missed Abortion | T/S |
| Diagnostic Laparoscopy | T/S |
| Perineorrhaphy | T/S |
| Loop electrocautery excision procedure | T/S |
| Vaginal resuspension | T/S |
| Operative hysteroscopy | T/S |



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5.2 The physician obtain informed consent for transfusion of blood and blood products:

- 5.2.1** It is the policy to obtain approved signed consent form to document that the consent process has occurred signed by the patient or legal representative in case of acceptance or refusal of transfusion treatment.
- 5.2.2** It is the exclusive duty and responsibility of the attending and/or treating physician.
- 5.2.3** The consent Will Be Valid For The Period Of Admission on every admission.
- 5.2.4** Before requesting a blood product for transfusion ,the physician must:
- 5.2.4.1 Explain the nature, risks/benefits and possible side effects of blood transfusion to the patient. And the alternatives to transfusion are discussed with the patient.
- 5.2.4.2 The consent states that the patient:
- a- Understands what medical action is recommended.
 - b- Is aware of the risks and benefits associated with the transfusion. The indication (s) or justification for giving a blood product should be documented in the patient's case notes



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c- Is also aware of the risks, and possible consequences of not receiving the recommended therapy.

d- The possible alternatives treatment modalities

e- Is given an opportunity to ask questions of a learned professional before providing consent..

5.2.4.3 The patient gives consent for the transfusion (or is given by his/her legal guardian) by signing the consent form. The physician , the patient /guardian and a witness(nurse or another physician) countersign the consent form .

5.2.5 The patient is must not be forced AND if he/ she is refusing the transfusion, Obtain the written consent of the patient.

5.2.6 The patient is also informed of his/her right to refuse the transfusion & recording a patient's refusal to receive blood or blood components in the patient's medical record.

5.2.7 If a patient is unable to give consent, a legally authorized representative or surrogate may do so

5.2.8 In cases when the patient/guardian refuses transfusion, the patient/guardian should sign in the refusal part of the consent form.

5.2.9 Where the patient is too young (<18 year) to give consent this should be explained to an adult with parental responsibility.



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5.2.10 In the case where mentally disordered patients refuse a transfusion, advice should be sought from the on-call duty psychiatrist.

5.2.11 If no one is available to provide consent and the need for transfusion is considered a medical emergency, the blood component may be administered based on the doctrine of implied consent. But the emergent need for transfusion should be carefully documented in the medical record.

5.2.12 in case of refusal of blood components transfusion, patient refusal part of the form must be filled as the physician evidence that he explained the complications and effects of not receiving blood components treatment and the patient /or guardian will take complete responsibility of refusing treatment and risks associated with it. the witness , name and signature, will co-sign The refusal consent.

5.2.13 Documentation of the consent process must be entered into the patient's medical record.

5.2.14 Patient Education and History

- a) The transfusionist (nurse or doctor starting the transfusion process) should educate the patient about reporting any symptoms that may be indicative of a reaction and how long the transfusion will take.



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- b) The patient's questions should be answered before the transfusion is started.
- c) It is important to collect a history from the patient before the component is ordered to assess previous transfusions and any adverse reactions.

5.3Iv Access, Administration Sets and Compatible Solutions

- 5.3.1** Whole blood and blood components shall be transfused using sterile, pyrogen free administration sets containing a filter (i.e. Adults: 170-260 microns).
- 5.3.2** Blood administration sets should be connected directly to the IV access site. Blood components shall not be piggy-backed into an existing line as it increases the risk of contamination and/or infusion of an incompatible IV fluid.
- 5.3.3** Blood component administration **should begin within thirty (30) minutes** from the time the product is released from temperature controlled storage.
- 5.3.4** Transfusions of blood components **shall not exceed four (4) hours** from the time of release from temperature controlled storage, refer to table.
- 5.3.5** Blood components that have been out of temperature controlled storage greater **than 30 minutes** shall not be returned to inventory



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or re-issued and shall be discarded by the transfusion service laboratory.

- 5.3.6** Administration sets shall be changed **after four consecutive units of red cells have been transfused**, if the administration set becomes occluded, at least once every 24 hours or according to manufacturer's recommendations.
- 5.3.7** Administration sets shall be changed between the administrations of different blood components.
- 5.3.8** Blood warming devices shall be validated and have a temperature sensing device and an audible alarm system.
- 5.3.9** Medication shall not be added directly to a blood component, blood product or to the administration set containing a blood component.
- 5.3.10** **0.9% sodium chloride** solution for IV use may be added to red blood cells on the request of the physician or if the administration set requires priming for blood components.
- 5.3.11** Lactated Ringer's should not be added to blood components as it may cause clotting due to calcium content.
- 5.3.12** Air shall not be introduced into the administration set or the blood components or blood products being transfused.
- 5.3.13** Blood components and blood products shall be **visually inspected** for clots, clumps or discoloration immediately before issue and



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the inspection documented. The expiry date shall be checked to ensure the blood component or blood product is not outdated.

5.3.14 Blood components and blood products (specifically red cells, platelets and cryoprecipitate) shall be mixed gently by inversion to re-suspend the product.

5.3.15 Transfusion flow rates should be indicated on the physician's order. If possible, transfusions should start slowly and the recipient observed for **the first 15 minutes** for any adverse effects of transfusion.

5.4 Transfusion of Blood Components: Prior to administration of blood transfusion, at least two (2) registered nurse or one (1) and (1) physician shall perform bedside check for the following data on the blood bag label, blood unit tag and patient's wrist band :

- Patient's Full Name.
- Medical Record Number.
- Blood or Blood Product's type and Serial Number.
- Blood Group and Compatibility.
- Expiration Date.
- The staff should perform the following:



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| Action | Rationale |
|---|--|
| 1. Prime the blood administration set with 0.9 % Normal Saline until all air bubbles flushes out and close the roller clamp. | Flushing with Normal Saline removes all air bubbles from the administration set. |
| 2. Invert the unit of blood/blood product at least three (3) times. | To equally distribute blood/ component. |
| 3. Following asepsis, remove protective covering from the port of the blood bag and spike with the blood administration set. | To prevent contamination. |
| 4. Connect to three-way stopcock and open the clamp. Start infusion slowly at 10 drops per minute or slower if condition demands. Close-off 0.9 % Normal Saline main line. | Only normal saline is compatible with blood/ blood product, others may cause hemolysis or changes in the RBC structure. Prevent backflow. |
| 5. Stay with the patient for the first 5 to 15 minutes of transfusion. | Most transfusion reactions occur within the first few minutes. |
| 6. Check and record vital signs every 15 minutes for the first hour and every 30 minutes thereafter until transfusion is completed. Observe patient for flushing, dyspnea, itching, hives/rash or any transfusion reaction. | Frequent monitoring will alert the staff nurse for any adverse reactions so that time management may be initiated. |
| 7. Stop the blood transfusion immediately for any noted transfusion reaction. Open the line for 0.9 % Normal Saline and refer to the doctor without delay. | Infusing normal saline clears the blood set of any remaining blood and keeps IV line patent for supportive measures in case of transfusion reaction. |
| 8. Document: <ul style="list-style-type: none"> • Date, time and name of the staff starting and ending the transfusion. • Names of individuals who verified patient's identity and the blood/ blood product details. • Any transfusion reaction and intervention done. • Record the amount of blood transfused in the Intake and Output Sheet. | For continuity of care and to provide a documentation of tracing blood or blood product transfusion procedure. |



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5.5post administration

5.5.1 The IV line shall be flushed following transfusion.

5.5.2 The blood component or blood product and administration set shall be disconnected.

5.5.3 Following completion of the transfusion, post transfusion information shall be documented on the compatibility label/tag and the patient's chart.

5.5.4 Red blood cell and platelet bags should be placed in a sealed plastic bag and kept for a minimum of 4 hours post-transfusion for investigation of suspected bacterial contamination.

5.5.5 Transfusion reactions are immediately reported and analyzed for preventive and corrective actions .Policy & procedure of management of adverse transfusion reaction should be applied.

6. Responsibility

6.1It is responsibility of transfusion service medical director and blood usage and transfusion committee for the initiation to review and revise/update this existing APP annually involving the guidelines the handling, use, and administration of blood products & also ensure strict compliance and implementation of this APP.

7. References

7.1Transfusion Services Manual of SOPs Training Guides and Competency Assessment Tools 2nd edition.



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- 7.2 Newfoundland and Labrador Provincial Blood Coordinating Program.
Guidelines for Blood Component Substitution in Adults. Version 3.0.
St. John's (NL).Newfoundland and Labrador Provincial Blood
Coordinating Program; 2010.
- 7.3 Technical Manual of American Association of Blood Banks 18th
edition, 2016.
- 7.4 Standards for Blood Bank and Transfusion Services .Bethesda, MD:
American Association of Blood Bank 30th edition, 2016.
- 7.5 The unified Practical Manual for Blood Banks in Arab Countries
(MOH) 2013.
- 7.6 CBAHI national standards for hospitals 3rd edition, 2015.



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8. Approvals:

| | Name | Title | Signature | Date |
|--------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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1. **Statement Of Purpose:**

The purpose of this policy is to provide guidance to the all transfusion service staff, bacteriology staff & medical and nursing staff in early detection of transfusion reaction to lessen severity of blood transfusion complications; these policies also provide guidance for actions to be taken in cases of adverse transfusion reaction.

2. **Definitions:**

2.1. Transfusion reaction an undesirable event occurring in patient during or after transfusion of blood product.

2.2. Acute Transfusion Reactions is a reaction that occurs during or within 24 hours of transfusion and can occur with any type of component. Acute reactions include acute hemolytic, febrile, allergic, Transfusion Related Acute Lung Injury (TRALI), volume overload, anaphylaxis, and bacterial infection etc.

2.3. Acute Hemolytic Transfusion Reaction (AHTR) is a type of transfusion reaction that is associated with intravascular hemolysis. It occurs very soon after the transfusion. It is also known as an "immediate hemolytic transfusion reaction".

2.4. Febrile Non-hemolytic Transfusion Reactions (FNHTR) it is a type of transfusion reaction that is associated with fever (rise of 1°C or more) but not related to red cell hemolysis. The reaction can be mediated by cytokines or antibodies to leucocyte antigens (HLA).



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2.5. Allergic Transfusion Reaction: is a reaction to donor plasma proteins.

The antibody-antigen reaction causes the release of histamine from mast cells and basophils, which leads to hives and itching.

2.6. Anaphylactic Reactions: mostly are observed in patients with hereditary deficiency of immunoglobulin A (IgA) and develop complement-binding with anti-IgA antibodies that cause anaphylaxis when exposed to donor's IgA.

2.7. Delayed Transfusion Reactions: Reactions occurring after 24 hours of transfusion reaction including delayed hemolysis, graft vs. host disease (GVHD) or infectious diseases.

2.8. Delayed Hemolytic Transfusion Reaction: (Extravascular) typically occurs when a patient has been previously sensitized by transfusion or pregnancy and their antibody level is not detectable in vitro by pre-transfusion compatibility testing.

2.9. Transfusion Transmitted Disease (TTD): Transmission of infectious disease from a donor's blood to patients which includes but not limited to:-

2.9.1. AIDS-Human Immunodeficiency Virus I and-II (HIV)

2.9.2. The Human T-Lymphotropic Virus I and -II (HTLV)

2.9.3. Hepatitis C (HCV)

2.9.4. Hepatitis B (HBV)

2.9.5. Malaria (MP)



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2.9.6. Syphilis (*Treponema pallidum*)

2.9.7. Bacteria and other parasites

2.10 **TRALI:** is defined as an acute lung injury caused by blood transfusion; specifically, if it occurs within the first six hours following a blood or its products transfusion

3. **Materials/Form(S):**

3.1. Transfusion Reaction Form.

3.2. Post transfusion EDTA Blood Specimen.

3.3. Blood Product unit which caused reaction including transfusion set attached to the bag.

3.4. OVAR (Occurrence, Variance Report) Form.

3.5. Corrective action form

3.6. Aerobic and anaerobic blood culture bottles

3.7. Materials required to perform Blood grouping DAT, Ab screen, and Crossmatch

4. **Policy Statement:**

4.1. It is the policy of transfusion laboratory to perform accurate management of adverse transfusion events which covers:

- a) Recognition and handling of adverse transfusion events.
- b) Reporting and monitoring of adverse transfusion events.

4.2. There is a process for management of suspected transfusion reactions which covers:



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- a) Clerical check of the identification information and records.
- b) Visual inspection of the blood product, pre and post transfusion samples.
- c) Initial immune-hematological testing and conditions for performing additional testing(minor/major cross-match, urine analysis, biochemistry, microbial culture).
- d) Conclusion and instructions for future transfusion.

4.3. Transfusion reaction reports are reviewed by the transfusion services medical director and the transfusion committee as following ;It is the policy of transfusion laboratory that; the monthly and annual report is reviewed by the laboratory director and submitted to the hospital TQM department as a quality indicator and submitted also to transfusion committee .

4.4. It is the policy of Hospital to report each case of transfusion reaction as an OVAR and send it to the blood bank for reporting to the TQM department.

4.5. It is the policy of transfusion laboratory that any adverse reaction or event experienced by a patient in association with a transfusion shall be regarded as a suspected transfusion reaction/complication.

4.6. Transfusion reaction investigations are STAT procedures so shall be completed as soon as possible.



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- 4.7. Fatal Transfusion Reaction and Acute Hemolytic Transfusion Reaction shall be reported to the treating physician without any delay, Medical Director, Director Blood Bank, and CEO of hospital Shall be informed.
- 4.8. The analysis-investigation shall be performed by a technologist, under supervision of a blood bank physician or by a physician.
- 4.9. It is the policy that in case of Immediate Complication where there are symptoms or findings suggestive of an acute transfusion reaction, the transfusion shall be immediately interrupted and evaluated. The evaluation shall not delay proper clinical management of the patient.

5. Procedure:

5.1. Nursing Procedure (Read this department to nurses if they don't know what to do):

- 5.1.1. Stop the infusion immediately; keep the line open with a slow infusion of saline.
- 5.1.2. Notify the treating physician immediately.
- 5.1.3. Re-Check the identification of the patient and the identification of the blood infused:
- 5.1.2.1. Patient Name and file number and verify that patient is correct patient



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5.1.2.2. Blood units information and be assure the unit is for the same patient

5.1.4. Monitor and document the vital signs.

5.1.5. Notify the transfusion service lab of the unit number(s) of the blood products implicated in the reaction.

5.1.6. Order a Transfusion Reaction Investigation procedure which includes:

5.1.6.1. Completely fill a Transfusion Reaction Form.

5.1.6.2. Copy of query unit Tag.

5.1.6.3. Extract 5 ml blood specimen in EDTA tube and send to the blood bank with filled transfusion reaction request, the blood unit which caused the reaction with attached transfusion set. Remove the needle from the set and close the tubes by clamps properly.

5.1.6.4. Send Urine specimens to Parasitology Lab department for free Hemoglobin, if hemolytic reaction is suspected.

5.1.6.5. Send blood culture to microbiology lab (especially if there is more than one degree rise in the patient's temperature).

5.1.6.6. Retain a copy of the Transfusion Reaction Form in the patient's chart.



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5.1.6.7. Ensure Blood sample is drawn STAT for the workup.

Sample must be drawn carefully to minimize mechanical hemolysis and must be properly labelled.

5.1.7. If transfusion is indicated prior to completion of the investigation, the physician must consult with the transfusion service Medical Director/Physician to determine safest approach.

5.2. Transfusion service laboratory Procedures:

5.2.1. Receive the transfusion reaction investigation request (if the request form is filled completely and properly).

5.2.2. Post transfusion Blood Specimen is there.

5.2.3. The blood unit caused transfusion reaction, properly closed with label.

5.2.4. Inform the assigned lab Physician.

5.2.5. Assigned Physician shall assign a technologist under his supervision to Check for Clerical mistakes:

5.2.5.1. Check the patient's name, medical record number, blood type, hospital/ ward, donor unit number, donor blood type and expiry date on all documents, blood specimens and blood product involved.

5.2.5.2. Record findings in transfusion reaction form.



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5.2.5.3. If any discrepancy is noted in documentation/clerical check, proceed as follows:

5.2.5.3.1. If there is evidence of a transfusion error, notify the Blood Bank medical Director, patient's physician immediately.

5.2.5.3.2. If there is indication of a mix-up of patient samples, miss-draw of patient, or mix- up of donor units, check other patient records over the same time period as there may be another patient at risk.

5.2.6. Perform visual inspection of post transfusion sample:

5.2.6.1. If there is hemolysis or jaundice, compare pre and post transfusion specimen for hemolysis and jaundice (yellow or brownish colouring). Record findings in the transfusion reaction form.

5.2.6.2. If hemolysis or jaundice is observed in post transfusion sample but not in the pre-transfusion sample, refer to transfusion service medical director for possible extended workup.

5.2.7. Send specimen for Microbial Culture from Blood unit if patient's temperature rose more than 1C above 37C:

5.2.7.1. Label aerobic and anaerobic blood culture bottles.



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5.2.7.2. Take 10-15 ml blood from the blood bag by pricking the hemostat of the unit aseptically.

5.2.7.3. Add 5-7 ml blood in both culture bottles

5.2.7.3.1. Generate the culture request.

5.2.7.3.2. Send the culture bottles to microbiology department; keep copy of request with records.

5.2.8. Serological Tests:

5.2.8.1. Perform ABO and Rh on blood bag and patient post transfusion sample.

5.2.8.2. Perform DAT on post transfusion patient sample.

5.2.8.3. Perform Antibody Screen and complete crossmatch on post transfusion sample.

5.2.8.4. If a discrepancy arises inform blood bank medical director, and Inform treating physician

5.2.8.5. If a discrepancy arises, or DAT reveals positive, test the pre-transfusion sample also.

5.2.8.6. If no discrepancy arises, record all findings and keep the record in transfusion reaction file.

5.2.9. If culture already sent to microbiology department, follow culture report after 48 hours and on 6th day; hand over the papers to medical director for finalization:



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5.2.9.1. If culture reveals growth, inform the blood medical director without any delay.

5.2.9.2. Send copy of the report to ward and file the papers transfusion reaction file.

5.2.10. Interpretation:

| Symptoms & Signs | Lab Results or Serology | Possible Interpretation |
|---|--|------------------------------------|
| Chills, fever , Hemoglobinuria hypertension, back pain, DIC (oozing from IV sites) pain along the infusion site with anxiety | - ABO discrepancy - DAT positive. -Hemolysis - Hemoglobinuria | Hemolytic transfusion Reaction. |
| Fever (>38.5°C), chills, headache, vomiting | -DAT Neg. (or-no change) - Culture Neg. -No discrepancy | Febrile Non Hemolytic |
| Urticaria, pruritus, flushing | -DAT Neg. (or-no change) - Culture Neg. -No discrepancy | Allergic Reaction |
| Hypotension, urticaria, bronchospasm Local edema, anxiety | -DAT Neg. or unchanged -No discrepancy | TRALI |

5.2.11. Documentation of the results of the entire investigations in the transfusion reaction work up form.



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6. Responsibility:

- 6.1. It is the responsibility of patient's clinical staff, doctors/nurses, to observe the patient keenly during blood transfusion and take immediate actions in case of a reaction.
- 6.2. It is the responsibility of patient's clinical staff, doctors/nurses, to coordinate with the transfusion service lab and send transfusion reaction investigation to it.
- 6.3. It is the responsibility of assigned technician or technologist to receive the request, blood unit and sample and hand over to blood bank physician.
- 6.4. It is the responsibility of assigned physician to assign a technologist to do the job under his direct supervision.
- 6.5. It is the responsibility of transfusion services medical director to review all transfusion reaction reports on transfusion committee. Compliance will be monitored and follow-up by the blood utilization committee.

7. References:

- 7.1. Standards for Blood Banks and Transfusion Services, 30th Edition, 2016.
- 7.2. American Association of Blood Banks Technical Manual, 18th Edition, 2014.








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7.3.Unified Arab Blood Bank Practical Procedure Manual, KSA
MOH, 3rd edition 2013 .

7.4.CBAHI national standards for hospitals 3rd edition, 2015.

8. Approvals:

| | Name | Title | Signature | Date |
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| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 14-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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1. Statement Of Purpose:

The purpose of this policy is to ensure clear traceability of all blood and blood components from donor to recipient.

2. Definition:

2.1 Traceability: The ability to follow the history of a blood product or service by means of recorded identification.

2.2 Blood Transfusion Transmitted Disease (TTD): A communicable disease which might be transfused from an infected blood donor to recipient of his/her blood.

3. Equipment/Material/Forms:

3.1 All adhesive labels for all components printed and pasted according to relevant transfusion services policies.

3.2 All documented (Hard Log Books or computer) steps from donor selection to final disposition of a blood product.

3.3. Product or donor information for which traceability is required.

4. Policy Statement:

4.1 It is the policy of transfusion service to have ability to trace all the steps involved from blood donation to its final disposition positively by having accurate and easily accessible data base in transfusion service.



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4.2 The transfusion service policies, procedures and data base will cover all steps required for a successful traceability in case of TTD look back for a blood donor or a TTD surveillance for a recipient of a blood product.

5. Procedure:

5.1 At The Transfusion Service Side:

5.1.1 Following steps shall be adopted to issue a blood to a patient :

5.1.1.1 The request for transfusion is received as per the policy.

5.1.1.2 Pre-transfusion testing is performed according to the policy.

5.1.1.3 Once compatible donation is selected, the new traceability tag is printed from computer system if available or prepared manually.



5.1.1.4 The tag is checked and then attached to the correct donation by means of a tamper-proof tie.



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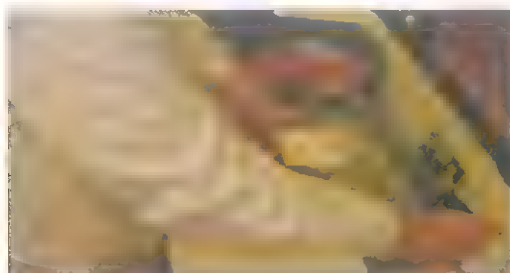
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5.1.1.5 The blood bag is over –wrapped and sent to the cross matched blood fridge or to the ward for transfusion.



5.1.1.6 When the blood is required for a patient, the transfusion service receptionist checks the label on the blood bag with the blood request form. Any discrepancies are investigated and resolved before issue.





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- 5.1.1.7** The staff member records the data of blood issue in issuing log book or in a computer program.



5.2 At The Patients Beside:

- 5.2.1** At the patients beside, at least two practitioners confirm the patient's details against the traceability tag and patients wristband. Check the bag for expiry date and any leaks, discoloration or clumping .If there are any discrepancies the transfusion should not proceed and Contact the transfusion service.
- 5.2.2** If the checks are satisfactory, Practitioner (1) signs the traceability tag before commencing.





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5.2.3 If the checks are satisfactory .Practitioner (2) signs traceability tag also before commencing the transfusion.



5.2.4 Set up transfusion as normal.



5.2.5 Once transfusion is completed paste tag in the relevant place in the patient's notes and/ or enters the data in computer system.



5.2.6 Both practitioners must sign the prescription form and when completed file in the appropriate place the patients record.



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- 5.2.7** If an adverse transfusion event happens: record the data in the patient's file and send transfusion reaction form and sample to transfusion service investigation.
- 5.2.8** If the blood product is not transfused return it to transfusion service lab within 30 mins.
- 5.2.9** Transfusion service lab receives returned blood products and register its data.

6. Responsibility:

6.1 It is the responsibility of clinical staff (nurses and physician) and transfusion lab staff to comply with this policy. Compliance will be monitored and follow-up by the blood utilization committee.


7. Reference:

- 7.1** Technical Manual of American Association of Blood Bank .18th edition 2014.
- 7.2** AABB Standard, 30th edition 2016.
- 7.3** The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
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Blood unit tag figure.

| | |
|--|---|
| Unit No: 3214699 | Component: Red Blood Cells |
| Signature 1: _____ | Date Given: _____ |
| Signature 2: _____ | Time Given: _____ |
| Patient Name FATMA AHMED SHERAHELI | Patient Computer No 00889580 |
| Patient Blood Group O Positive | Blood Component Red Blood Cells |
| Unit No 3214699 | Donor Blood Group O Positive |
|  * 3 2 1 4 6 9 9 * | |
| THIS BLOOD COMPONENT HAS BEEN TESTED AND FOUND COMPATIBLE FOR THE ABOVE LISTED PATIENT. | |



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| <u>TITLE</u> Look Back Policy. | | | |
| <u>EFFECTIVE DATE</u> 04- 06 -2018 | <u>REVISION DATE:</u> 03- 06- 2020 | <u>INDEX NO:</u> APP-LB-BB-44 -V1 | <u>NUMBER OF PAGES:</u> 5 |
| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide the guidance to transfusion service laboratory staff to take part in Look Back process in case a blood donor reveals TTD test positive having previous blood donations.

2. Definitions:

2.1. Look Back is the process of identifying, notifying, investigating and documenting cases of recipients of blood or blood components from donors who are subsequently found to have infected with transfusion transmissible disease.

3. Materials:

3.1 Blood donor's units Log Book/Computer System if available.

3.2 Blood issue Book / Computer System if available.

4. Policy Statement:

4.1. It is the policy of transfusion service to participate (through the blood transfusion committee & with cooperation of central blood bank that transfusion service in hospital make service agreement with) ,to look back transfusion of blood products from a donor who reveals infective for TTD on current testing if requested by the central blood bank.

4.2. The process for investigation of donors subsequently found to have transfusion transmissible disease on current donation (Look Back)ensures the following:

- a. Prompt quarantine of available components from the same donor



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- b. Prompt identification of the recipients.
- c. Prompt notification of the facility where the transfusion was conducted (if applicable).
- d. Prompt notification of the patient's physician and/or infection control.
- e. Investigation and follow-up of recipients.
- f. Reporting the investigation results (internally and externally), as applicable.

4.3 The Look back will be extended for:

- 4.3.1 One Year for Syphilis.
- 4.3.2 10 years for HCV.
- 4.3.3 Indefinite period for HIV and HTLV.
- 4.3.4 5 years for HBsAg and HBc Antibodies Positive with HBs Antibody Negative.

4.4 If recipients of units donated 12 months before the last known negative test are tested and found to be negative for the marker in question, look back shall not be extended for further time since the earlier recipients are more likely not at risk of infectivity.



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5. **Procedure:**

5.1. The transfusion service lab receive an official letter from central blood bank that performed (TTD); about previous negative unit number from the implicated donor.

5.2. Quarantine any in-date implicated units from same donors especially FFP and cryoppt from inventory. Return the implicated units to central blood bank with official letter.

5.3. The transfusion service lab activate traceability policy for implicated units, trace recipients of these implicated units.

5.4. Inform/Counsel the patient's physician and request him to counsel the patient to test his blood for suspected marker. If one year old recipient reveals the test non-reactive, limit look back to one year.

5.5. REPORT (OVAR) **Internally** to blood transfusion committee and **Externally** to Riyadh health affair & on official hemovigilance MOH website.

5.6. Inform to infection control department if the case is proved.

6. **Responsibility:**

6.1 It is responsibility of transfusion service laboratory Technician to participate in the look back process, maintains record of look back.



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6.2 It is the responsibility of physician assigned in the area to assure implementation of policies and procedure, Compliance will be monitored and follow-up by the blood utilization committee.






7. References:

- 7.1. CBAHI National Standards for Clinical Laboratory & Blood Banks, 2015.
- 7.2. CAP Checklist TRM, 2016.
- 7.3. CBAHI national standards for hospitals 3rd edition, 2015.



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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> TTD Surveillances. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide the guidance to transfusion service laboratory staff to take part in TTD SURVEILLANCES process in case a recipient a of blood products becomes reactive for TTD test.

2. Definitions:

2.1. Transfusion Transmitted Disease (TTD) Surveillance is a process of investigations that initiated if a patient reveals TTD marker result reactive after a blood product transfusion. It is called also **(Recipient Initiated Look Back Process)**.

2.2. Look Back is the process of tracing of blood recipients who have received blood from a previously negative, screened donor who has subsequently tested positive for an infectious disease **(TTD)**. It is called also **(Donor Initiated Look Back Process)**.

3. Materials:

- 3.1.** Blood donor's units Log Book/Computer System if available.
- 3.2.** Blood issue Book / Computer System if available.
- 3.3.** Previous & recent laboratory results (vial markers/bacterial infection) of transfused patient.



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4. Policy Statement:

4.1 It is the policy of transfusion service to participate (through the blood transfusion committee & with cooperation of central blood bank that transfusion service in hospital make service agreement with), in the development and implementation of a process for the investigation of suspected cases of post-transfusion infection. The process for the investigation of suspected cases of post-transfusion infection ensures the following:

4.1.1 Prompt identification of the implicated donors.

4.1.2 Prompt notification of the collecting facility (if applicable).

4.1.3 Prompt quarantine of available components from the implicated donors.

4.1.4 Investigating the implicated donors.

4.1.5 Assigning appropriate deferrals to the implicated donors.

4.1.6 Reporting the investigation results (internally and externally), as applicable.

4.2 If blood products will be the cause; the transfusion service shall assure to identify, treat and counsel other recipients of such donor's blood products.

4.3 If recipients of units donated 12 months before the last known negative test are tested and found to be negative for the marker in question, look



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back shall not be extended for further time since the earlier recipients are more likely not at risk of infectivity.

5. Procedure:

- 5.1.** The treating physician report a case of patient that has an infection which may be related to transfusion (TTD) with all his documents required; including Previous & recent laboratory results (viral markers/bacterial infection) of transfused patient.
- 5.2.** Identify all blood products transfused to that patient from records.
- 5.3.** Check the inventory & its records to assure that if the transfusion service lab have other products from the same implicated donors.
- 5.4.** Activate traceability policy if needed.
- 5.5.** Quarantine of available components from the same implicated donors from inventory.
- 5.6.** Make an OVAR & an official letter to the central blood bank that performed the (TTD) tests to check its records for status of all blood products implicated. Return the implicated quarantined units to central blood bank with an official letter.
- 5.7.** If a reactive donor's product was released and issued by mistake then inform treating physician to council and test the patient, REPORT (OVAR) **Internally** to blood transfusion committee and **Externally** to Riyadh health affair & on official hemovigilance MOH website.



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5.8. If there was no mistake in release: Identify all suspected donors and ask the central blood bank officially to call them for re-testing.

5.9. If all suspected donors prove non-reactive on retesting report, document and stop the process.

5.10. If any of suspected donors proves reactive on retesting; activate look back policy (with cooperation of central blood bank) for such donor.

5.11. Inform to infection control department if the case is proved.

6. Responsibility:

6.1. It is responsibility of transfusion service laboratory technician to participate in TTD surveillance process & maintain record of TTDs surveillance.

6.2. It is the responsibility of physician assigned in the area to assure implementation of policies and procedure, Compliance will be monitored and follow-up by the blood utilization committee.

7. References:

7.1. CBAHI National Standards for Clinical Laboratory & Blood Banks, 2015.

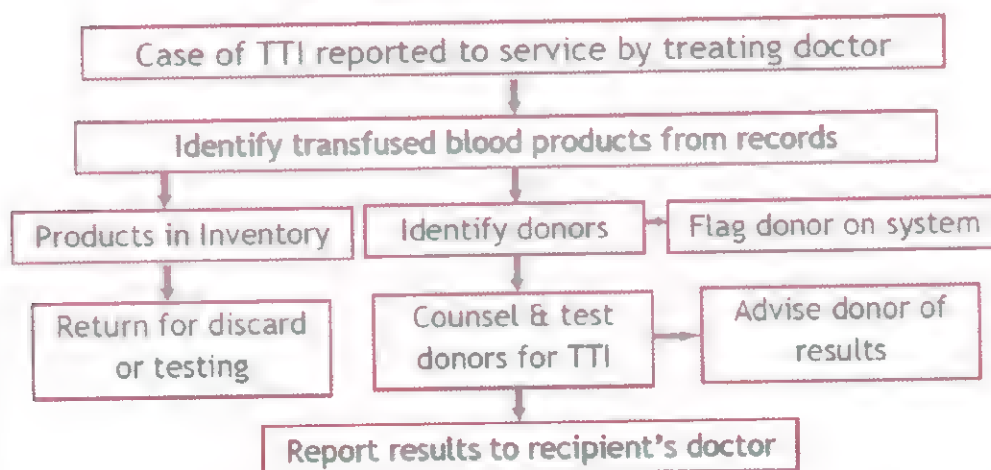
7.2. CAP Checklist TRM, 2016.

7.3. CBAHI national standards for hospitals 3rd edition, 2015.



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Process: Recipient Initiated Look Back





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8. Approvals:

| | Name | Title | Signature | Date |
|-----------------|----------------------|---|---|-----------|
| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9/4/2018 |
| | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 12-4-2018 |
| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
| Reviewed By: | Dr. Kamelia Salah | Blood Bank Quality Manager Riyadh Regional Lab |  | 19-4-2018 |
| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



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| <u>TITLE</u> Retention Of Documents. | | | |
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| <u>APPLIES TO:</u> Transfusion Service Laboratory staff. | | | |

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to all transfusion service lab staff and medical record staff to maintain retention of different transfusion service laboratory documents.

2. Definitions:

2.1 Records Retention is the practice of maintaining the records of an organization from the time they are created up to their eventual disposal. This may include classifying, storing, securing, and destruction or archival preservation of records

3. Equipment/Material/Forms:

- 3.1 All documents of relevant transfusion service policies & procedures.
- 3.2 Steel Boxes.
- 3.3 File List Form.

4. Policy Statement:

4.1 It is the policy of transfusion service laboratory to implement certain retention periods of different transfusion service laboratory documents as follow:

4.2 Permanent retention of records :

- a) Patient's blood group discrepancies.
- b) Clinically significant antibodies for the patient.
- c) Significant adverse transfusion reactions.
- d) Patient with special transfusion requirements.



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- e) Patient transfusion history.
- f) Transfusion transmitted diseases investigations records.
- g) Final disposition of blood / blood components.

4.3 10 Years Retention:

- a. Quality control records.
- b. Pre-transfusion testing blood group-AB screening –CT-ICT results for patients.
- c. Cross matching interpretation. (Cross Match Work Sheets and request).

4.4 5 Years Retention:

- a. Supply records as for reagents. Blood components received and issued to other hospitals.
- b. Any changes in procedures.
- c. Quality indicators records.
- d. Staff qualification, training and competency.
- e. Safety records.
- f. Corrective and preventive action.
- g. Records of storage temperatures for blood products.

5. Procedure: NA.



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6. Responsibility:

6.1 It is the responsibility of assigned technician to maintain the record with the assistant of medical record department.

6.2 It is the responsibility of laboratory director to insure proper implementation of the policy & procedure.

7. References:

7.1.Standards for Blood Bank and Transfusion Services .Bethesda, MD:
American Association of Blood Bank 30th edition, 2016.






7.2.The unified Practical Manual for Blood Banks in Arab Countries
(MOH) 2013.

7.3.CBAHI national standards for hospitals 3rd edition, 2015.



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| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
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| | Dr. Mona Mohi El Din | Blood Bank Physician Lab.& blood bank administration, Riyadh health affair |  | 15/4/2018 |
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| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |



TITLE Role Of Transfusion Service Lab Representative In Blood Transfusion Committee.

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APPLIES TO: Transfusion Service Laboratory staff.

1. Statement Of Purpose:

The purpose of this policy is to provide guidance to transfusion service lab representative about his role in presentation of data in blood transfusion committee to evaluate and formulate the ways for a better utilization of blood & blood components and to avoid unnecessary use, wastage and expiry of blood & blood components.

2. Definitions:

2.1 Blood utilization: The use of blood and its components.

2.2 Cross match-to-Transfusion Ratio: one of transfusion service quality indicators ,inexperienced staff may order more blood than needed, which may increase the outdate rates. Available shelf life decreases each time a unit is held or cross matched for a patient who does not use it. (C: T) ratio greater than 2 usually indicates excessive cross match requests.

3. Equipment/Material/Forms:

3.1transfusion service statistics.

3.2 Laboratory Reports of blood adverse transfusion events.

4. Policy Statement:

4.1 It is policy of transfusion service to develop, review collaboratively with the blood utilization committee, policies & procedures of guiding the handling, use, and administration of blood and blood products .



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APPLIES TO: Transfusion Service Laboratory staff.

4.2 It is policy of transfusion service to participate (through the blood transfusion committee) in the development of a process for the management of adverse or suspected transfusion events. This process for the management of adverse transfusion events covers:

- a. Recognition and handling of adverse transfusion events.
- b. Reporting and monitoring of adverse transfusion events.
- c. Conclusion and instructions for future transfusion.
- d. Transfusion reaction reports are reviewed by the transfusion services medical director and the transfusion committee.

4.3 It is policy of transfusion service to participate (through the blood transfusion committee) in the development and implementation of a process for the investigation of suspected cases of post-transfusion infection (TTD Surveillances & look back policies).

4.4 It is policy of transfusion service to prepare every month , transfusion service statistics and quality indicators to be presented in the blood transfusion committee for discussion as follow:

- a. **Cross match-to-Transfusion Ratio** :Cross match units - to-Transfusion units for the same requests (for each hospital ward and total for the hospital).



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APPLIES TO: Transfusion Service Laboratory staff.

- b. **Appropriateness of the transfusion requests** (for each hospital ward and total for the hospital).
- c. **Out dated units &Wastage units with related causes**
(return un transfused units from wards after 30 minutes, storage failure) .

5. Procedure: NA

6. Responsibility:

6.1it is responsibility of transfusion service medical director/ representative to prepare the required data to be discussed in blood usage and transfusion committee to ensure strict compliance and implementation of related policies and procedures.






7. References

- 7.1 Technical Manual of American Association of Blood Banks 18th edition, 2016.
- 7.2 Standards for Blood Bank and Transfusion Services .Bethesda, MD: American Association of Blood Bank 30th edition, 2016.
- 7.3 The unified Practical Manual for Blood Banks in Arab Countries (MOH) 2013.
- 7.4 CBAHI national standards for hospitals 3rd edition, 2015.



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| <u>TITLE</u> Role Of Transfusion Service Lab Representative In Blood Transfusion Committee. | | | |
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| Prepared By: | Mr. Mohammed Khalid | Blood Bank Quality Control Officer Riyadh Regional Lab |  | 9-4-2018 |
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| Approved By: | Dr. Kamel Al-Dossari | Laboratory Director Of Riyadh Regional Lab & Lab.& blood bank administration, Riyadh health affair. |  | 1-5-2018 |